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OSMITROL Injection (Mannitol Injection, USP) in AVIVA Plastic Container

For Therapeutic Use Only

Description

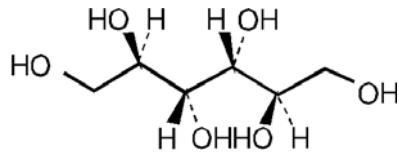
Osmitrol Injection (Mannitol Injection, USP) is a sterile, nonpyrogenic solution of Mannitol, USP in a single dose container for intravenous administration. It contains no antimicrobial agents. Mannitol** is a six carbon sugar alcohol prepared commercially by the reduction of dextrose. Although virtually inert metabolically in humans, it occurs naturally in fruits and vegetables. Mannitol is an obligatory osmotic diuretic. The pH may have been adjusted with sodium hydroxide and/or hydrochloric acid. Composition, osmolarity, and pH are shown in Table 1.

Table 1	Composition			
	Size (mL)	**Mannitol, USP (g/L)	*Osmolarity (mOsmol/L) (calc)	pH
5% OSMITROL Injection (5% Mannitol Injection, USP)	1000	50	274	5.5 (4.5 TO 7.0)
10% OSMITROL Injection (10% Mannitol Injection, USP)	500	100	549	5.5 (4.5 TO 7.0)
	1000			
15% OSMITROL Injection (15% Mannitol Injection, USP)	500	150	823	5.5 (4.5 TO 7.0)
20% OSMITROL Injection (20% Mannitol Injection, USP)	250	200	1098	5.5 (4.5 TO 7.0)
	500			

*Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L.
Administration of substantially hypertonic solutions (≥ 600 mOsmol/L) may cause vein damage.

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Mannitol

The flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of paclitaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

The suitability of the container materials has been established through biological evaluations, which have shown the container passes Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system.

The flexible container is a closed system, and air is prefilled in the container to facilitate drainage. The container does not require entry of external air during administration.

The container has two ports: one is the administration outlet port for the attachment of an intravenous administration set and the other port has a medication site for addition of supplemental medication (See Directions for Use). The primary function of the overwrap is to protect the container from the physical environment.

Clinical Pharmacology

Osmitrol Injection (Mannitol Injection, USP) is one of the nonelectrolyte, obligatory, osmotic diuretics. It is freely filterable at the renal glomerulus, only poorly reabsorbed by the renal tubule, not secreted by the tubule, and is pharmacologically inert.

Mannitol, when administered intravenously, exerts its osmotic effect as a solute of relatively small molecular size being largely confined to the extracellular space. Only relatively small amounts of the dose administered is metabolized. Mannitol is readily diffused through the glomerulus of the kidney over a wide range of normal and impaired kidney function. In this fashion, approximately 80% of a 100 gram dose of mannitol will appear in the urine in three hours with lesser amounts thereafter. Even at peak concentrations, mannitol will exhibit less than 10% of tubular reabsorption and is not secreted by tubular cells. Mannitol will hinder tubular reabsorption of water and enhance excretion of sodium

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and chloride by elevating the osmolarity of the glomerular filtrate.

This increase in extracellular osmolarity effected by the intravenous administration of mannitol will induce the movement of intracellular water to the extracellular and vascular spaces. This action underlies the role of mannitol in reducing intracranial pressure, intracranial edema, and elevated intraocular pressure.

Indications and Usage

Osmitrol Injection (Mannitol Injection, USP) is indicated for:

The promotion of diuresis, in the prevention and/or treatment of the oliguric phase of acute renal failure before irreversible renal failure becomes established;

The reduction of intracranial pressure and treatment of cerebral edema by reducing brain mass;

The reduction of elevated intraocular pressure when the pressure cannot be lowered by other means, and promoting the urinary excretion of toxic substances.

Contraindications

Osmitrol Injection (Mannitol Injection, USP) is contraindicated in patients with:

Well established anuria due to severe renal disease, severe pulmonary congestion or frank pulmonary edema, active intracranial bleeding except during craniotomy, severe dehydration, Progressive renal damage or dysfunction after institution of mannitol therapy, including increasing oliguria and azotemia, and progressive heart failure or pulmonary congestion after institution of mannitol therapy.

Warnings

In patients with severe impairment of renal function, a test dose should be utilized (see Dosage and Administration). A second test dose may be tried if there is an inadequate response, but no more than two test doses should be attempted.

The obligatory diuretic response following rapid infusion of 15% or 20% mannitol injection may further aggravate preexisting hemoconcentration. Excessive loss of water and electrolytes may lead to serious imbalances. Serum sodium and potassium should be carefully monitored during mannitol administration.

If urine output continues to decline during mannitol infusion, the patient's clinical status should be closely reviewed and mannitol infusion suspended if necessary. Accumulation of mannitol may result in overexpansion of the extracellular fluid which may intensify existing or latent congestive heart failure.

Excessive loss of water and electrolytes may lead to serious imbalances. With continued administration of mannitol, loss of water in excess of electrolytes can cause hypernatremia. Electrolyte measurements, including sodium and potassium, are therefore, of vital importance in monitoring the

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infusion of mannitol.

Osmotic nephrosis, a reversible vacuolization of the tubules of unknown clinical significance, may proceed to severe irreversible nephrosis, so that the renal function must be closely monitored during mannitol infusion.

Precautions

General

Do not connect flexible plastic containers of intravenous solutions in series, i.e., do not piggyback connections. Such use could result in air embolism due to residual air being drawn from one container before administration of the fluid from a secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

The cardiovascular status of the patient should be carefully evaluated before rapidly administering mannitol since sudden expansion of the extracellular fluid may lead to fulminating congestive heart failure.

Shift of sodium free intracellular fluid into the extracellular compartment following mannitol infusion may lower serum sodium concentration and aggravate preexisting hyponatremia.

By sustaining diuresis, mannitol administration may obscure and intensify inadequate hydration or hypovolemia.

Electrolyte free mannitol should not be given conjointly with blood. If it is essential that blood be given simultaneously, at least 20 mEq of sodium chloride should be added to each liter of mannitol solution to avoid pseudoagglutination.

When exposed to low temperatures, solutions of mannitol may crystallize. Concentrations greater than 15% have a greater tendency to crystallization. Inspect for crystals prior to administration. If crystals are visible, redissolve by warming the solution up to 70°C, with agitation. Allow the solution to cool to room temperature before reinspection for crystals. Administer intravenously using sterile, **filter-type** administration set.

Laboratory Tests

Although blood levels of mannitol can be measured, there is little if any clinical virtue in doing so.

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The appropriate monitoring of blood levels of sodium and potassium; degree of hemoconcentration or hemodilution, if any; indices of renal, cardiac and pulmonary function are paramount in avoiding excessive fluid and electrolyte shifts. The routine features of physical examination and clinical chemistries suffice in achieving an adequate degree of appropriate patient monitoring.

Drug Interaction

Studies have not been conducted to evaluate drug/drug or drug/food interactions with Osmitol Injection (Mannitol Injection, USP).

Carcinogenesis, mutagenesis, impairment of fertility

Studies with Osmitol Injection (Mannitol Injection, USP) have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy: Teratogenic Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with mannitol. It is also not known whether mannitol can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Mannitol should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Studies have not been conducted to evaluate the effects of Osmitol Injection (Mannitol Injection, USP) on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when mannitol is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in children below the age of 12 have not been established.

Usage in Children

Dosage requirements for patients 12 years of age and under have not been established.

Geriatric Use

Clinical studies of Osmitol Injection (Mannitol Injection, USP) did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in the responses between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely

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to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Adverse Reactions

Extensive use of mannitol over the last several decades has produced recorded adverse events, in a variety of clinical settings, that are isolated or idiosyncratic in nature. None of these adverse reactions have occurred with any great frequency nor with any security in attributing them to mannitol.

The inability to clearly exclude the drug related nature of such events in these isolated reports prompts the necessity to list the reactions that have been observed in patients during or following mannitol infusion. In this fashion, patients have exhibited nausea, vomiting, rhinitis, local pain, skin necrosis and thrombophlebitis at the site of infection, chills, dizziness, urticaria, hypotension, hypertension, tachycardia, fever and angina-like chest pains.

Of far greater clinical significance is a variety of events that are related to inappropriate recognition and monitoring of fluid shifts. These are not intrinsic adverse reactions to the drug but the consequence of manipulating osmolarity by any agency in a therapeutically inappropriate manner. Failure to recognize severe impairment of renal function with the high likelihood of non-diuretic response can lead to aggravated dehydration of tissues and increased vascular fluid load. Induced diuresis in the presence of preexisting hemoconcentration and preexisting deficiency of water and electrolytes can lead to serious imbalances. Expansion of the extracellular space can aggravate cardiac decompensation or induce it in the presence of latent heart failure. Pulmonary congestion or edema can be seriously aggravated with the expansion of the extracellular and therefore intravascular fluid load. Hemodilution and dilution of the extracellular fluid space by osmotic shift of water can induce or aggravate preexisting hyponatremia.

If unrecognized, such fluid and/or electrolyte shift can produce the reported adverse reactions of pulmonary congestion, acidosis, electrolyte loss, dryness of mouth, thirst, edema, headache, blurred vision, convulsions and congestive cardiac failure.

These are not truly adverse reactions to the drug and can be appropriately prevented by evaluation of degree of renal failure with a test dose response to mannitol when indicated; evaluation of hypervolemia and hypovolemia; sodium and potassium levels; hemodilution or hemoconcentration; and evaluation of renal, cardiac and pulmonary function at the onset of therapy.

Dosage and Administration

Osmitol Injection (Mannitol Injection, USP) should be administered only by intravenous infusion. The total dosage, concentration, and rate of administration should be governed by the nature and severity of the condition being treated, fluid requirement, and urinary output. The usual adult dosage ranges from 20 to 100 g in a 24 hour period, but in most instances an adequate response will be achieved at a dosage of approximately 50 to 100 g in a 24 hour period. The rate of administration is usually adjusted to maintain a urine flow of at least 30 to 50 mL/hour. This outline of administration

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and dosage is only a general guide to therapy.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Use of a final filter is recommended during administration of all parenteral solutions, where possible. Do not administer unless solution is clear and seal is intact.

Test Dose: A test dose of mannitol should be given prior to instituting Osmitol Injection (Mannitol Injection, USP) therapy for patients with marked oliguria, or those believed to have inadequate renal function. Such a test dose may be approximately 0.2 g/kg body weight (about 75 mL of a 20% solution or 100 mL of a 15% solution) infused in a period of three to five minutes to produce a urine flow of at least 30 to 50 mL/hour. If urine flow does not increase, a second test dose may be given; if there is an inadequate response, the patient should be reevaluated.

Prevention of Acute Renal Failure (Oliguria): When used during cardiovascular and other types of surgery, 50 to 100 g of mannitol as a 5, 10, or 15% solution may be given. The concentration will depend upon the fluid requirements of the patient.

Treatment of Oliguria: The usual dose for treatment of oliguria is 100 g administered as a 15 or 20% solution.

Reduction of Intraocular Pressure: A dose of 1.5 to 2.0 g/kg as a 20% solution (7.5 to 10 mL/kg) or as a 15% solution (10 to 13 mL/kg) may be given over a period as short as 30 minutes in order to obtain a prompt and maximal effect. When used preoperatively the dose should be given one to one and one-half hours before surgery to achieve maximal reduction of intraocular pressure before operation.

Reduction of Intracranial Pressure: Usually a maximum reduction in intracranial pressure in adults can be achieved with a dose of 0.25 g/kg given not more frequently than every six to eight hours. An osmotic gradient between the blood and cerebrospinal fluid of approximately 10 mOsmols will yield a satisfactory reduction in intracranial pressure.

Adjunctive Therapy for Intoxications: As an agent to promote diuresis in intoxications, 5%, 10%, 15% or 20% mannitol is indicated. The concentration will depend upon the fluid requirement and urinary output of the patient.

Measurement of glomerular filtration rate by creatinine clearance may be useful for determination of dosage.

All injections in AVIVA containers are intended for intravenous administration using sterile equipment.

The use of supplemental additive medication is not recommended.

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How Supplied

Osmitrol Injection (Mannitol Injection, USP) in AVIVA plastic containers is available as follows:

Code	Size (mL)	NDC	Product Name
6E5604	1000	0338-6300-04	5% Osmitrol Injection (5% Mannitol Injection, USP)
6E5613	500	0338-6301-03	10% Osmitrol Injection
6E5614	1000	0338-6301-04	(10% Mannitol Injection, USP)
6E5623	500	0338-6302-03	15% Osmitrol Injection (15% Mannitol Injection, USP)
6E5632	250	0338-6303-02	20% Osmitrol Injection
6E5633	500	0338-6303-03	(20% Osmitrol Injection)

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure up to 40°C does not adversely affect the product.

Directions for Use of AVIVA Plastic Container

To Open

Tear overwrap down side at slit and remove solution container. Moisture and some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired.

Preparation for Administration

Caution: Do not use plastic containers in series connections.

Caution: Use only with a non-vented set or a vented set with the vent closed.

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

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Sodium Chloride Injection, USP in AVIVA Plastic Container

Description

Sodium Chloride Injection, USP is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment in single dose containers for intravenous administration. It contains no antimicrobial agents. The pH is 5.5 (4.5 to 7.0). Composition, osmolarity, and ionic concentration are shown below.

0.45% Sodium Chloride Injection, USP contains 4.5 g/L Sodium Chloride, USP (NaCl) with an osmolarity of 154 mOsmol/L (calc). It contains 77 mEq/L sodium and 77 mEq/L chloride.

0.9% Sodium Chloride Injection, USP contains 9 g/L Sodium Chloride USP (NaCl) with an osmolarity of 308 mOsmol/L (calc). It contains 154 mEq/L sodium and 154 mEq/L chloride.

The flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of paclitaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

The suitability of the container materials has been established through biological evaluations, which have shown the container passes Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system.

The flexible container is a closed system, and air is prefilled in the container to facilitate drainage. The container does not require entry of external air during administration.

The container has two ports: one is the administration outlet port for attachment of an intravenous administration set and the other port has a medication site for addition of supplemental medication (See Directions for Use). The primary function of the overwrap is to protect the container from the physical environment.

Clinical Pharmacology

Sodium Chloride Injection, USP has value as a source of water and electrolytes. It is capable of inducing diuresis depending on the clinical condition of the patient.

Indications and Usage

Sodium Chloride Injection, USP is indicated as a source of water and electrolytes.

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0.9% Sodium Chloride Injection, USP is also indicated for use as a priming solution in hemodialysis procedures.

Contraindications

None known.

Warnings

Sodium Chloride Injection, USP should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

In patients with diminished renal function, administration of Sodium Chloride Injection, USP may result in sodium retention.

Precautions

General

Do not connect flexible plastic containers of intravenous solutions in series, i.e., do not piggyback connections. Such use could result in air embolism due to residual air being drawn from one container before administration of the fluid from a secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

Laboratory Tests

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

Drug Interactions

Caution must be exercised in the administration of Sodium Chloride Injection, USP to patients receiving corticosteroids or corticotropin.

Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with Sodium Chloride Injection, USP.

Carcinogenesis, mutagenesis, impairment of fertility

Studies with Sodium Chloride Injection, USP have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

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Pregnancy: Teratogenic Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with Sodium Chloride Injection, USP. It is also known whether Sodium Chloride Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium Chloride Injection, USP should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Studies have not been conducted to evaluate the effects of Sodium Chloride Injection, USP on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Sodium Chloride Injection, USP is administered to a nursing woman.

Pediatric Use

Safety and effectiveness of Sodium Chloride Injection, USP in pediatric patients have not been established by adequate and well controlled trials, however, the use of Sodium Chloride solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

Geriatric Use

Clinical studies of Sodium Chloride Injection, USP did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in the responses between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Adverse Reactions

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation, and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

Dosage and Administration

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100, 16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091, 16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055, 17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065, 17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029, 19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

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As directed by a physician. Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Do not administer unless solution is clear and seal is intact.

All injections in AVIVA plastic containers are intended for intravenous administration using sterile equipment.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

How Supplied

The available sizes of each injection in AVIVA plastic containers are shown below:

Code	Size (mL)	NDC	Product Name
6E1313	500	0338-6333-03	0.45% Sodium Chloride Injection, USP
6E1314	1000	0338-6333-04	
6E1356	250	0338-6333-02	
6E1322	250	0338-6304-02	0.9% Sodium Chloride Injection, USP
6E1323	500	0338-6304-03	
6E1324	1000	0338-6304-04	

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C/77°F); brief exposure up to 40°C(104°F) does not adversely affect the product.

Directions for Use of AVIVA plastic container

To Open

Tear overwrap down side at slit and remove solution container. Moisture and some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

Caution: Do not use plastic containers in series connections.

Caution: Use only with a non-vented set or a vented set with the vent closed.

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16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091,
16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055,
17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065,
17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029,
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1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Additives may be incompatible.

To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in-use position and continue administration.

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Deerfield, IL 60015 USA

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For Product Information

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Dextrose and Sodium Chloride Injection, USP in AVIVA Plastic Container

Description

Dextrose and Sodium Chloride Injection, USP is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment and caloric supply in single dose containers for intravenous administration. It contains no antimicrobial agents. Composition, osmolarity, pH, ionic concentration and caloric content are shown in Table 1.

Table 1

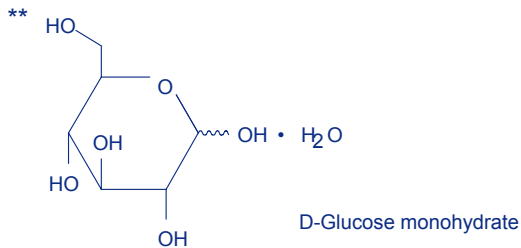
	Size (mL)	Composition (g/L)		*Osmolarity (mOsmol/L) (calc.)	pH	Ionic Concentration (mEq/L)		Caloric Content (kcal/L)
		** Dextrose Hydrous, USP	Sodium Chloride, USP (NaCl)			Sodium	Chloride	
2.5% Dextrose and 0.45% Sodium Chloride Injection, USP	500 1000	25	4.5	280	4.5 (3.2 to 6.5)	77	77	85
5% Dextrose and 0.2% Sodium Chloride Injection, USP	250 500 1000	50	2	321	4.0 (3.2 to 6.5)	34	34	170
5% Dextrose and 0.33% Sodium Chloride Injection, USP	250 500 1000	50	3.3	365	4.0 (3.2 to 6.5)	56	56	170
5% Dextrose and 0.45% Sodium Chloride Injection, USP	250 500 1000	50	4.5	406	4.0 (3.2 to 6.5)	77	77	170
5% Dextrose and 0.9% Sodium Chloride Injection, USP	250 500 1000	50	9	560	4.0 (3.2 to 6.5)	154	154	170
10% Dextrose and 0.9% Sodium Chloride Injection, USP	500 1000	100	9	813	4.0 (3.2 to 6.5)	154	154	340

*Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L.

Administration of substantially hypertonic solutions (≥ 600 mOsmol/L) may cause vein damage.

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16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091,
16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055,
17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065,
17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029,
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The flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of paclitaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

The suitability of the container materials has been established through biological evaluations, which have shown the container passes Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system.

The flexible container is a closed system, and air is prefilled in the container to facilitate drainage. The container does not require entry of external air during administration.

The container has two ports: one is the administration outlet port for attachment of an intravenous administration set and the other port has a medication site for addition of supplemental medication (See Directions for Use). The primary function of the overwrap is to protect the container from the physical environment.

Clinical Pharmacology

Dextrose and Sodium Chloride Injection, USP has value as a source of water, electrolytes, and calories. It is capable of inducing diuresis depending on the clinical condition of the patient.

Indications and Usage

Dextrose and Sodium Chloride Injection, USP is indicated as a source of water, electrolytes, and calories.

Contraindications

Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn products.

Warnings

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Dextrose and Sodium Chloride Injection, USP should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

Dextrose injections with low electrolyte concentrations should not be administered simultaneously with blood through the same administration set because of the possibility of pseudoagglutination or hemolysis. The container label for these injections bears the statement: Do not administer simultaneously with blood.

The intravenous administration of Dextrose and Sodium Chloride Injection, USP can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injections. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injections.

Excessive administration of Dextrose and Sodium Chloride Injection, USP may result in significant hypokalemia.

In patients with diminished renal function, administration of Dextrose and Sodium Chloride Injection, USP may result in sodium retention.

Precautions

General

Do not connect flexible plastic containers of intravenous solutions in series, i.e., do not piggyback connections. Such use could result in air embolism due to residual air being drawn from one container before administration of the fluid from a secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

Dextrose and Sodium Chloride Injection, USP should be used with caution in patients with overt or subclinical diabetes mellitus.

Laboratory Tests

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

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Drug Interactions

Caution must be exercised in the administration of Dextrose and Sodium Chloride Injection, USP to patients receiving corticosteroids or corticotropin.

Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with Dextrose and Sodium Chloride Injection, USP.

Carcinogenesis, mutagenesis, impairment of fertility

Studies with Dextrose and Sodium Chloride Injection, USP have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy: Teratogenic Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with Dextrose and Sodium Chloride Injection, USP. It is also known whether Dextrose and Sodium Chloride Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Dextrose and Sodium Chloride Injection, USP should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Studies have not been conducted to evaluate the effects of Dextrose and Sodium Chloride Injection, USP on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Dextrose and Sodium Chloride Injection, USP is administered to a nursing mother.

Pediatric Use

Safety and effectiveness of Dextrose and Sodium Chloride Injection, USP in pediatric patients have not been established by adequate and well controlled trials, however, the use of dextrose and sodium chloride solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

In very low birth weight infants, excessive or rapid administration of dextrose injection may result in increased serum osmolality and possible hemorrhage.

Geriatric Use

Clinical studies of Dextrose and Sodium Chloride Injection, USP did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in the responses between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100, 16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091, 16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055, 17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065, 17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029, 19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

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at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Adverse Reactions

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

Dosage and Administration

As directed by a physician. Dosage is dependent upon the age, weight, and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Do not administer unless solution is clear and seal is intact.

All injections in AVIVA plastic containers are intended for intravenous administration using sterile equipment.

As reported in the literature, the dosage and constant infusion rate of intravenous dextrose must be selected with caution in pediatric patients, particularly neonates and low weight infants, because of the increased risk of hyperglycemia/hypoglycemia.

Additives may be incompatible. Complete information is not available.

Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

How Supplied

Dextrose and Sodium Chloride Injection, USP in AVIVA plastic container is supplied as follows:

Code	Size (mL)	NDC	Product Name
6E1023	500	0338-6315-03	2.5% Dextrose and 0.45% Sodium Chloride
6E1024	1000	0338-6315-04	Injection, USP

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100, 16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091, 16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055, 17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065, 17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029, 19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

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6E1092	250	0338-6310-02	5% Dextrose and 0.2% Sodium Chloride
6E1093	500	0338-6310-03	Injection, USP
6E1094	1000	0338-6310-04	
6E1082	250	0338-6309-02	5% Dextrose and 0.33% Sodium Chloride
6E1083	500	0338-6309-03	Injection, USP
6E1084	1000	0338-6309-04	
6E1072	250	0338-6308-02	5% Dextrose and 0.45% Sodium Chloride
6E1073	500	0338-6308-03	Injection, USP
6E1074	1000	0338-6308-04	
6E1062	250	0338-6305-02	5% Dextrose and 0.9% Sodium Chloride
6E1063	500	0338-6305-03	Injection, USP
6E1064	1000	0338-6305-04	
6E1163	500	0338-6314-03	10% Dextrose and 0.9% Sodium Chloride
6E1164	1000	0338-6314-04	Injection, USP

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure up to 40°C does not adversely affect the product.

Directions for Use of AVIVA plastic container

To Open

Tear overwrap down side at slit and remove solution container. Moisture and some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

Caution: Do not use plastic containers in series connections.

Caution: Use only with a non-vented set or a vented set with the vent closed.

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Additives may be incompatible.

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100,
16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091,
16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055,
17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065,
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19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

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To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

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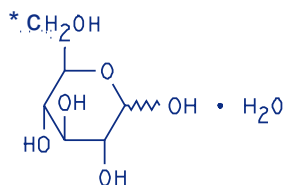
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Lactated Ringer's and 5% Dextrose Injection, USP in AVIVA Plastic Container

Description

Lactated Ringer's and 5% Dextrose Injection, USP is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment and caloric supply in a single dose container for intravenous administration. Each 100 mL contains 5 g Dextrose Hydrous, USP*; 600 mg Sodium Chloride, USP (NaCl); 310 mg Sodium Lactate (C₃H₅NaO₃); 30 mg of Potassium Chloride, USP (KCl); and 20 mg Calcium Chloride, USP (CaCl₂•2H₂O). It contains no antimicrobial agents. Approximate pH 5.0 (4.0 to 6.5).



D-Glucopyranose monohydrate

Lactated Ringer's and 5% Dextrose Injection, USP administered intravenously has value as a source of water, electrolytes, and calories. One liter has an ionic concentration of 130 mEq sodium, 4 mEq potassium, 2.7 mEq calcium, 109 mEq chloride and 28 mEq lactate. The osmolarity is 525 mOsmol/L (calc). Normal physiologic range is approximately 280 to 310 mOsmol/L. Administration of substantially hypertonic solutions may cause vein damage. The caloric content is 180 kcal/L.

The flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of paclitaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

The suitability of the container materials has been established through biological evaluations, which have shown the container passes Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system.

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The flexible container is a closed system, and air is prefilled in the container to facilitate drainage. The container does not require entry of external air during administration.

The container has two ports: one is the administration outlet port for attachment of an intravenous administration set and the other port has a medication site for addition of supplemental medication (See Directions for Use). The primary function of the overwrap is to protect the container from the physical environment.

Clinical Pharmacology

Lactated Ringer's and 5% Dextrose Injection, USP has value as a source of water, electrolytes, and calories. It is capable of inducing diuresis depending on the clinical condition of the patient.

Lactated Ringer's and 5% Dextrose Injection, USP produces a metabolic alkalinizing effect. Lactate ions are metabolized ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

Indications and Usage

Lactated Ringer's and 5% Dextrose Injection, USP is indicated as a source of water, electrolytes and calories or as an alkalinizing agent.

Contraindications

Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn products.

Warnings

Lactated Ringer's and 5% Dextrose Injection, USP should be used with great care. If at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

Lactated Ringer's and 5% Dextrose Injection, USP should be used with great care, if at all, in patients with hyperkalemia, severe renal failure, and in conditions in which potassium retention is present.

Lactated Ringer's and 5% Dextrose Injection, USP should be used with great care in patients with metabolic or respiratory alkalosis. The administration of lactate ions should be done with great care in those conditions in which there is an increased level or an impaired utilization of these ions, such as severe hepatic insufficiency.

Lactated Ringer's and 5% Dextrose Injection, USP should not be administered simultaneously with blood through the same administration set because of the likelihood of coagulation.

The intravenous administration of Lactated Ringer's and 5% Dextrose Injection, USP can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the

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electrolyte concentrations of the injection. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection.

In patients with diminished renal function, administration of Lactated Ringer's and 5% Dextrose Injection, USP may result in sodium or potassium retention.

Lactated Ringer's and 5% Dextrose Injection, USP is not for use in the treatment of lactic acidosis.

Precautions

General

Do not connect flexible plastic containers of intravenous solutions in series, i.e., do not piggyback connections. Such use could result in air embolism due to residual air being drawn from one container before administration of the fluid from a secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

Lactated Ringer's and 5% Dextrose Injection, USP should be used with caution in patients with overt or subclinical diabetes mellitus.

Laboratory Tests

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

Drug Interactions

Caution must be exercised in the administration of Lactated Ringer's and 5% Dextrose Injection, USP to patients receiving corticosteroids or corticotropin.

Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with Lactated Ringer's and 5% Dextrose Injection, USP.

Carcinogenesis, mutagenesis, impairment of fertility

Studies with Lactated Ringer's and 5% Dextrose Injection, USP have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy: Teratogenic Effects

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Pregnancy Category C. Animal reproduction studies have not been conducted with Lactated Ringer's and 5% Dextrose Injection, USP. It is also not known whether Lactated Ringer's and 5% Dextrose Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Lactated Ringer's and 5% Dextrose Injection, USP should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Studies have not been conducted to evaluate the effects of Lactated Ringer's and 5% Dextrose Injection, USP on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Lactated Ringer's and 5% Dextrose Injection, USP is administered to a nursing mother.

Pediatric Use

Safety and effectiveness of Lactated Ringer's and 5% Dextrose Injection, USP in pediatric patients have not been established by adequate and well controlled trials, however, the use of lactated ringer's and dextrose solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

In very low birth weight infants, excessive or rapid administration of dextrose injection may result in increased serum amorality and possible hemorrhage.

Geriatric Use

Clinical studies of Lactated Ringer's and 5% Dextrose Injection, USP did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in the responses between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Adverse Reactions

Allergic reactions or anaphylactic symptoms such as localized or generalized urinary and purities; per orbital, facial, and/or laryngeal edema; coughing, sneezing, and/or difficulty with breathing have been

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reported during administration of Lactated Ringer's and 5% Dextrose Injection, USP. The reporting frequency of these signs and symptoms is higher in women during pregnancy.

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasations, and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

Dosage and Administration

As directed by a physician. Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Do not administer unless solution is clear and seal is intact.

All injections in AVIVA plastic containers are intended for intravenous administration using sterile equipment.

As reported in the literature, the dosage and constant infusion rate of intravenous dextrose must be selected with caution in pediatric patients, particularly neonates and low weight infants, because of the increased risk of hyperglycemia/hypoglycemia.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

How Supplied

Lactated Ringer's and 5% Dextrose Injection, USP in AVIVA plastic containers is available as shown below:

Code	Size	NDC
6E2073	500 mL	NDC 0338-6306-03
6E2074	1000 mL	NDC 0338-6306-04

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure up to 40°C does not adversely affect the product.

Directions for Use of AVIVA plastic container

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To Open

Tear overwrap down side at slit and remove solution container. Moisture and some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

Caution: Do not use plastic containers in series connections.

Caution: Use only with a non-vented set or a vented set with the vent closed.

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Additives may be incompatible.

To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

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Lactated Ringer's Injection, USP in AVIVA Plastic Container

Description

Lactated Ringer's Injection, USP is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment in single dose containers for intravenous administration. It contains no antimicrobial agents. Composition, osmolarity, pH, ionic concentration and caloric content are shown in Table 1.

Table 1

	Size (mL)	Composition (g/L)				Osmolarity (mOsmol/L) (calc)	pH	Ionic Concentration (mEq/L)					Caloric Content (kcal/L)
		Sodium Chloride, USP, (NaCl)	Sodium Lactate, (C ₃ H ₅ NaO ₃)	Potassium Chloride, USP, (KCl)	Calcium Chloride, USP (CaCl ₂ ·2H ₂ O)			Sodium	Potassium	Calcium	Chloride	Lactate	
Lactated Ringer's Injection, USP	250	6	3.1	0.3	0.2	273	6.5 (6.0 to 7.5)	130	4	2.7	109	28	9
	500												
	1000												

The flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of paclitaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

The suitability of the container materials has been established through biological evaluations, which have shown the container passes Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system.

The flexible container is a closed system, and air is prefilled in the container to facilitate drainage. The container does not require entry of external air during administration.

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The container has two ports: one is the administration outlet port for attachment of an intravenous administration set and the other port has a medication site for addition of supplemental medication (See Directions for Use). The primary function of the overwrap is to protect the container from the physical environment.

Clinical Pharmacology

Lactated Ringer's Injection, USP has value as a source of water and electrolytes. It is capable of inducing diuresis depending on the clinical condition of the patient.

Lactated Ringer's Injection, USP produces a metabolic alkalinizing effect. Lactate ions are metabolized ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

Indications and Usage

Lactated Ringer's Injection, USP is indicated as a source of water and electrolytes or as an alkalinizing agent.

Contraindications

None known

Warnings

Lactated Ringer's Injection, USP should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

Lactated Ringer's Injection, USP should be used with great care, if at all, in patients with hyperkalemia, severe renal failure, and in conditions in which potassium retention is present.

Lactated Ringer's Injection, USP should be used with great care in patients with metabolic or respiratory alkalosis. The administration of lactate ions should be done with great care in those conditions in which there is an increased level or an impaired utilization of these ions, such as severe hepatic insufficiency.

Lactated Ringer's Injection, USP should not be administered simultaneously with blood through the same administration set because of the likelihood of coagulation.

The intravenous administration of Lactated Ringer's Injection, USP can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentration of the injections. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injections.

In patients with diminished renal function, administration of Lactated Ringer's Injection, USP may result in sodium or potassium retention. Lactated Ringer's injection, USP is not for use in the treatment of lactic acidosis.

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Precautions

General

Do not connect flexible plastic containers of intravenous solutions in series, i.e., do not piggyback connections. Such use could result in air embolism due to residual air being drawn from one container before administration of the fluid from a secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

Lactated Ringer's Injections, USP must be used with caution. Excess administration may result in metabolic alkalosis.

Laboratory Test

CLINICAL EVALUATION AND PERIODIC LABORATORY DETERMINATIONS ARE NECESSARY TO MONITOR CHANGES IN FLUID BALANCE, ELECTROLYTE CONCENTRATIONS, AND ACID BASE BALANCE DURING PROLONGED PARENTERAL THERAPY OR WHENEVER THE CONDITION OF THE PATIENT WARRANTS SUCH EVALUATION.

Drug Interactions

Caution must be exercised in the administration of Lactated Ringer's Injection, USP to patients receiving corticosteroids or corticotropin.

Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with Lactated Ringer's Injection, USP.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY

STUDIES WITH LACTATED RINGER'S INJECTION, USP HAVE NOT BEEN PERFORMED TO EVALUATE CARCINOGENIC POTENTIAL, MUTAGENIC POTENTIAL, OR EFFECTS ON FERTILITY.

Pregnancy: Teratogenic Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with Lactated Ringer's Injection, USP. It is also not known whether Lactated Ringer's Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Lactated Ringer's Injection, USP should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Studies have not been conducted to evaluate the effects of Lactated Ringer's Injection, USP on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

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Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Lactated Ringer's Injection, USP is administered to a nursing woman.

Pediatric Use

Safety and effectiveness of Lactated Ringer's Injection, USP in pediatric patients have not been established by adequate and well controlled trials, however, the use of electrolyte solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

Geriatric Use

Clinical studies of Lactated Ringer's Injection, USP did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and concomitant disease or drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Adverse Reactions

Allergic reactions or anaphylactoid symptoms such as localized or generalized urticaria and pruritis; periorbital, facial, and/or laryngeal edema; coughing, sneezing, and/or difficulty with breathing have been reported during administration of Lactated Ringer's Injection, USP. The reporting frequency of these signs and symptoms is higher in women during pregnancy.

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of infection, extravasation, and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

Dosage and Administration

As directed by a physician. Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations.

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Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Do not administer unless solution is clear and seal is intact.

All injections in AVIVA plastic containers are intended for intravenous administration using sterile equipment.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

How Supplied

Lactated Ringer's Injection, USP in AVIVA plastic container is available as follows:

Code	Size (mL)	NDC
6E2322	250	0338-6307-02
6E2323	500	0338-6307-03
6E2324	1000	0338-6307-04

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure up to 40° C does not adversely affect the product.

Directions for Use of AVIVA plastic container

To Open

Tear overwrap down side at slit and remove solution container. Moisture and some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

Caution: Do not use plastic containers in series connections.

Caution: Use only with a non-vented set or a vented set with the vent closed.

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Additives may be incompatible.

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To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in-use position and continue administration.

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Dextrose and Sodium Chloride Injection, USP in AVIVA Plastic Container

Description

Dextrose and Sodium Chloride Injection, USP is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment and caloric supply in single dose containers for intravenous administration. It contains no antimicrobial agents. Composition, osmolarity, pH, ionic concentration and caloric content are shown in Table 1.

Table 1

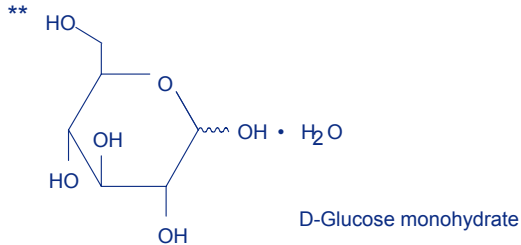
	Size (mL)	Composition (g/L)		*Osmolarity (mOsmol/L) (calc.)	pH	Ionic Concentration (mEq/L)		Caloric Content (kcal/L)
		** Dextrose Hydrous, USP	Sodium Chloride, USP (NaCl)			Sodium	Chloride	
2.5% Dextrose and 0.45% Sodium Chloride Injection, USP	500 1000	25	4.5	280	4.5 (3.2 to 6.5)	77	77	85
5% Dextrose and 0.2% Sodium Chloride Injection, USP	250 500 1000	50	2	321	4.0 (3.2 to 6.5)	34	34	170
5% Dextrose and 0.33% Sodium Chloride Injection, USP	250 500 1000	50	3.3	365	4.0 (3.2 to 6.5)	56	56	170
5% Dextrose and 0.45% Sodium Chloride Injection, USP	250 500 1000	50	4.5	406	4.0 (3.2 to 6.5)	77	77	170
5% Dextrose and 0.9% Sodium Chloride Injection, USP	250 500 1000	50	9	560	4.0 (3.2 to 6.5)	154	154	170
10% Dextrose and 0.9% Sodium Chloride Injection, USP	500 1000	100	9	813	4.0 (3.2 to 6.5)	154	154	340

*Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L.

Administration of substantially hypertonic solutions (≥ 600 mOsmol/L) may cause vein damage.

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The flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of paclitaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

The suitability of the container materials has been established through biological evaluations, which have shown the container passes Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system.

The flexible container is a closed system, and air is prefilled in the container to facilitate drainage. The container does not require entry of external air during administration.

The container has two ports: one is the administration outlet port for attachment of an intravenous administration set and the other port has a medication site for addition of supplemental medication (See Directions for Use). The primary function of the overwrap is to protect the container from the physical environment.

Clinical Pharmacology

Dextrose and Sodium Chloride Injection, USP has value as a source of water, electrolytes, and calories. It is capable of inducing diuresis depending on the clinical condition of the patient.

Indications and Usage

Dextrose and Sodium Chloride Injection, USP is indicated as a source of water, electrolytes, and calories.

Contraindications

Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn products.

Warnings

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Dextrose and Sodium Chloride Injection, USP should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

Dextrose injections with low electrolyte concentrations should not be administered simultaneously with blood through the same administration set because of the possibility of pseudoagglutination or hemolysis. The container label for these injections bears the statement: Do not administer simultaneously with blood.

The intravenous administration of Dextrose and Sodium Chloride Injection, USP can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injections. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injections.

Excessive administration of Dextrose and Sodium Chloride Injection, USP may result in significant hypokalemia.

In patients with diminished renal function, administration of Dextrose and Sodium Chloride Injection, USP may result in sodium retention.

Precautions

General

Do not connect flexible plastic containers of intravenous solutions in series, i.e., do not piggyback connections. Such use could result in air embolism due to residual air being drawn from one container before administration of the fluid from a secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

Dextrose and Sodium Chloride Injection, USP should be used with caution in patients with overt or subclinical diabetes mellitus.

Laboratory Tests

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

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Drug Interactions

Caution must be exercised in the administration of Dextrose and Sodium Chloride Injection, USP to patients receiving corticosteroids or corticotropin.

Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with Dextrose and Sodium Chloride Injection, USP.

Carcinogenesis, mutagenesis, impairment of fertility

Studies with Dextrose and Sodium Chloride Injection, USP have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy: Teratogenic Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with Dextrose and Sodium Chloride Injection, USP. It is also known whether Dextrose and Sodium Chloride Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Dextrose and Sodium Chloride Injection, USP should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Studies have not been conducted to evaluate the effects of Dextrose and Sodium Chloride Injection, USP on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Dextrose and Sodium Chloride Injection, USP is administered to a nursing mother.

Pediatric Use

Safety and effectiveness of Dextrose and Sodium Chloride Injection, USP in pediatric patients have not been established by adequate and well controlled trials, however, the use of dextrose and sodium chloride solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

In very low birth weight infants, excessive or rapid administration of dextrose injection may result in increased serum osmolality and possible hemorrhage.

Geriatric Use

Clinical studies of Dextrose and Sodium Chloride Injection, USP did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in the responses between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting

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at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Adverse Reactions

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

Dosage and Administration

As directed by a physician. Dosage is dependent upon the age, weight, and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Do not administer unless solution is clear and seal is intact.

All injections in AVIVA plastic containers are intended for intravenous administration using sterile equipment.

As reported in the literature, the dosage and constant infusion rate of intravenous dextrose must be selected with caution in pediatric patients, particularly neonates and low weight infants, because of the increased risk of hyperglycemia/hypoglycemia.

Additives may be incompatible. Complete information is not available.

Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

How Supplied

Dextrose and Sodium Chloride Injection, USP in AVIVA plastic container is supplied as follows:

Code	Size (mL)	NDC	Product Name
6E1023	500	0338-6315-03	2.5% Dextrose and 0.45% Sodium Chloride
6E1024	1000	0338-6315-04	Injection, USP

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6E1092	250	0338-6310-02	5% Dextrose and 0.2% Sodium Chloride
6E1093	500	0338-6310-03	Injection, USP
6E1094	1000	0338-6310-04	
6E1082	250	0338-6309-02	5% Dextrose and 0.33% Sodium Chloride
6E1083	500	0338-6309-03	Injection, USP
6E1084	1000	0338-6309-04	
6E1072	250	0338-6308-02	5% Dextrose and 0.45% Sodium Chloride
6E1073	500	0338-6308-03	Injection, USP
6E1074	1000	0338-6308-04	
6E1062	250	0338-6305-02	5% Dextrose and 0.9% Sodium Chloride
6E1063	500	0338-6305-03	Injection, USP
6E1064	1000	0338-6305-04	
6E1163	500	0338-6314-03	10% Dextrose and 0.9% Sodium Chloride
6E1164	1000	0338-6314-04	Injection, USP

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure up to 40°C does not adversely affect the product.

Directions for Use of AVIVA plastic container

To Open

Tear overwrap down side at slit and remove solution container. Moisture and some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

Caution: Do not use plastic containers in series connections.

Caution: Use only with a non-vented set or a vented set with the vent closed.

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Additives may be incompatible.

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To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

Baxter Healthcare Corporation

Deerfield, IL 60015 USA

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Dextrose and Sodium Chloride Injection, USP in AVIVA Plastic Container

Description

Dextrose and Sodium Chloride Injection, USP is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment and caloric supply in single dose containers for intravenous administration. It contains no antimicrobial agents. Composition, osmolarity, pH, ionic concentration and caloric content are shown in Table 1.

Table 1

	Size (mL)	Composition (g/L)		*Osmolarity (mOsmol/L) (calc.)	pH	Ionic Concentration (mEq/L)		Caloric Content (kcal/L)
		** Dextrose Hydrates, USP	Sodium Chloride, USP (NaCl)			Sodium	Chloride	
2.5% Dextrose and 0.45% Sodium Chloride Injection, USP	500 1000	25	4.5	280	4.5 (3.2 to 6.5)	77	77	85
5% Dextrose and 0.2% Sodium Chloride Injection, USP	250 500 1000	50	2	321	4.0 (3.2 to 6.5)	34	34	170
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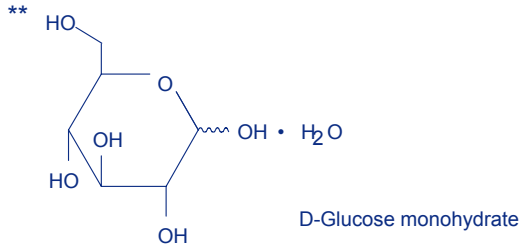
*Normal

physiologic osmolarity range is approximately 280 to 310 mOsmol/L.

Administration of substantially hypertonic solutions (≥ 600 mOsmol/L) may cause vein damage.

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The flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of paclitaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

The suitability of the container materials has been established through biological evaluations, which have shown the container passes Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system.

The flexible container is a closed system, and air is prefilled in the container to facilitate drainage. The container does not require entry of external air during administration.

The container has two ports: one is the administration outlet port for attachment of an intravenous administration set and the other port has a medication site for addition of supplemental medication (See Directions for Use). The primary function of the overwrap is to protect the container from the physical environment.

Clinical Pharmacology

Dextrose and Sodium Chloride Injection, USP has value as a source of water, electrolytes, and calories. It is capable of inducing diuresis depending on the clinical condition of the patient.

Indications and Usage

Dextrose and Sodium Chloride Injection, USP is indicated as a source of water, electrolytes, and calories.

Contraindications

Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn products.

Warnings

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Dextrose injections with low electrolyte concentrations should not be administered simultaneously with blood through the same administration set because of the possibility of pseudoagglutination or hemolysis. The container label for these injections bears the statement: Do not administer simultaneously with blood.

The intravenous administration of Dextrose and Sodium Chloride Injection, USP can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injections. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injections.

Excessive administration of Dextrose and Sodium Chloride Injection, USP may result in significant hypokalemia.

In patients with diminished renal function, administration of Dextrose and Sodium Chloride Injection, USP may result in sodium retention.

Precautions

General

Do not connect flexible plastic containers of intravenous solutions in series, i.e., do not piggyback connections. Such use could result in air embolism due to residual air being drawn from one container before administration of the fluid from a secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

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Drug Interactions

Caution must be exercised in the administration of Dextrose and Sodium Chloride Injection, USP to patients receiving corticosteroids or corticotropin.

Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with Dextrose and Sodium Chloride Injection, USP.

Carcinogenesis, mutagenesis, impairment of fertility

Studies with Dextrose and Sodium Chloride Injection, USP have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy: Teratogenic Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with Dextrose and Sodium Chloride Injection, USP. It is also known whether Dextrose and Sodium Chloride Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Dextrose and Sodium Chloride Injection, USP should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Studies have not been conducted to evaluate the effects of Dextrose and Sodium Chloride Injection, USP on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

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It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Dextrose and Sodium Chloride Injection, USP is administered to a nursing mother.

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In very low birth weight infants, excessive or rapid administration of dextrose injection may result in increased serum osmolality and possible hemorrhage.

Geriatric Use

Clinical studies of Dextrose and Sodium Chloride Injection, USP did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in the responses between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting

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at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Adverse Reactions

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

Dosage and Administration

As directed by a physician. Dosage is dependent upon the age, weight, and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Do not administer unless solution is clear and seal is intact.

All injections in AVIVA plastic containers are intended for intravenous administration using sterile equipment.

As reported in the literature, the dosage and constant infusion rate of intravenous dextrose must be selected with caution in pediatric patients, particularly neonates and low weight infants, because of the increased risk of hyperglycemia/hypoglycemia.

Additives may be incompatible. Complete information is not available.

Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

How Supplied

Dextrose and Sodium Chloride Injection, USP in AVIVA plastic container is supplied as follows:

Code	Size (mL)	NDC	Product Name
6E1023	500	0338-6315-03	2.5% Dextrose and 0.45% Sodium Chloride
6E1024	1000	0338-6315-04	Injection, USP

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100, 16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091, 16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055, 17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065, 17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029, 19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

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6E1092	250	0338-6310-02	5% Dextrose and 0.2% Sodium Chloride
6E1093	500	0338-6310-03	Injection, USP
6E1094	1000	0338-6310-04	
6E1082	250	0338-6309-02	5% Dextrose and 0.33% Sodium Chloride
6E1083	500	0338-6309-03	Injection, USP
6E1084	1000	0338-6309-04	
6E1072	250	0338-6308-02	5% Dextrose and 0.45% Sodium Chloride
6E1073	500	0338-6308-03	Injection, USP
6E1074	1000	0338-6308-04	
6E1062	250	0338-6305-02	5% Dextrose and 0.9% Sodium Chloride
6E1063	500	0338-6305-03	Injection, USP
6E1064	1000	0338-6305-04	
6E1163	500	0338-6314-03	10% Dextrose and 0.9% Sodium Chloride
6E1164	1000	0338-6314-04	Injection, USP

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure up to 40°C does not adversely affect the product.

Directions for Use of AVIVA plastic container

To Open

Tear overwrap down side at slit and remove solution container. Moisture and some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

Caution: Do not use plastic containers in series connections.

Caution: Use only with a non-vented set or a vented set with the vent closed.

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Additives may be incompatible.

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100,
16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091,
16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055,
17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065,
17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029,
19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

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To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

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Dextrose and Sodium Chloride Injection, USP in AVIVA Plastic Container

Description

Dextrose and Sodium Chloride Injection, USP is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment and caloric supply in single dose containers for intravenous administration. It contains no antimicrobial agents. Composition, osmolarity, pH, ionic concentration and caloric content are shown in Table 1.

Table 1

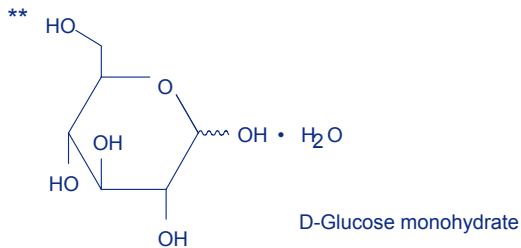
	Size (mL)	Composition (g/L)		*Osmolarity (mOsmol/L) (calc.)	pH	Ionic Concentration (mEq/L)		Caloric Content (kcal/L)
		** Dextrose Hydrous, USP	Sodium Chloride, USP (NaCl)			Sodium	Chloride	
2.5% Dextrose and 0.45% Sodium Chloride Injection, USP	500 1000	25	4.5	280	4.5 (3.2 to 6.5)	77	77	85
5% Dextrose and 0.2% Sodium Chloride Injection, USP	250 500 1000	50	2	321	4.0 (3.2 to 6.5)	34	34	170
5% Dextrose and 0.33% Sodium Chloride Injection, USP	250 500 1000	50	3.3	365	4.0 (3.2 to 6.5)	56	56	170
5% Dextrose and 0.45% Sodium Chloride Injection, USP	250 500 1000	50	4.5	406	4.0 (3.2 to 6.5)	77	77	170
5% Dextrose and 0.9% Sodium Chloride Injection, USP	250 500 1000	50	9	560	4.0 (3.2 to 6.5)	154	154	170
10% Dextrose and 0.9% Sodium Chloride Injection, USP	500 1000	100	9	813	4.0 (3.2 to 6.5)	154	154	340

*Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L.

Administration of substantially hypertonic solutions (≥ 600 mOsmol/L) may cause vein damage.

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100, 16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091, 16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055, 17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065, 17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029, 19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

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The flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of paclitaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

The suitability of the container materials has been established through biological evaluations, which have shown the container passes Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system.

The flexible container is a closed system, and air is prefilled in the container to facilitate drainage. The container does not require entry of external air during administration.

The container has two ports: one is the administration outlet port for attachment of an intravenous administration set and the other port has a medication site for addition of supplemental medication (See Directions for Use). The primary function of the overwrap is to protect the container from the physical environment.

Clinical Pharmacology

Dextrose and Sodium Chloride Injection, USP has value as a source of water, electrolytes, and calories. It is capable of inducing diuresis depending on the clinical condition of the patient.

Indications and Usage

Dextrose and Sodium Chloride Injection, USP is indicated as a source of water, electrolytes, and calories.

Contraindications

Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn products.

Warnings

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100, 16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091, 16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055, 17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065, 17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029, 19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

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Dextrose and Sodium Chloride Injection, USP should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

Dextrose injections with low electrolyte concentrations should not be administered simultaneously with blood through the same administration set because of the possibility of pseudoagglutination or hemolysis. The container label for these injections bears the statement: Do not administer simultaneously with blood.

The intravenous administration of Dextrose and Sodium Chloride Injection, USP can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injections. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injections.

Excessive administration of Dextrose and Sodium Chloride Injection, USP may result in significant hypokalemia.

In patients with diminished renal function, administration of Dextrose and Sodium Chloride Injection, USP may result in sodium retention.

Precautions

General

Do not connect flexible plastic containers of intravenous solutions in series, i.e., do not piggyback connections. Such use could result in air embolism due to residual air being drawn from one container before administration of the fluid from a secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

Dextrose and Sodium Chloride Injection, USP should be used with caution in patients with overt or subclinical diabetes mellitus.

Laboratory Tests

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100, 16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091, 16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055, 17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065, 17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029, 19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

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Drug Interactions

Caution must be exercised in the administration of Dextrose and Sodium Chloride Injection, USP to patients receiving corticosteroids or corticotropin.

Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with Dextrose and Sodium Chloride Injection, USP.

Carcinogenesis, mutagenesis, impairment of fertility

Studies with Dextrose and Sodium Chloride Injection, USP have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy: Teratogenic Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with Dextrose and Sodium Chloride Injection, USP. It is also known whether Dextrose and Sodium Chloride Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Dextrose and Sodium Chloride Injection, USP should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Studies have not been conducted to evaluate the effects of Dextrose and Sodium Chloride Injection, USP on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Dextrose and Sodium Chloride Injection, USP is administered to a nursing mother.

Pediatric Use

Safety and effectiveness of Dextrose and Sodium Chloride Injection, USP in pediatric patients have not been established by adequate and well controlled trials, however, the use of dextrose and sodium chloride solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

In very low birth weight infants, excessive or rapid administration of dextrose injection may result in increased serum osmolality and possible hemorrhage.

Geriatric Use

Clinical studies of Dextrose and Sodium Chloride Injection, USP did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in the responses between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting

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at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Adverse Reactions

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

Dosage and Administration

As directed by a physician. Dosage is dependent upon the age, weight, and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Do not administer unless solution is clear and seal is intact.

All injections in AVIVA plastic containers are intended for intravenous administration using sterile equipment.

As reported in the literature, the dosage and constant infusion rate of intravenous dextrose must be selected with caution in pediatric patients, particularly neonates and low weight infants, because of the increased risk of hyperglycemia/hypoglycemia.

Additives may be incompatible. Complete information is not available.

Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

How Supplied

Dextrose and Sodium Chloride Injection, USP in AVIVA plastic container is supplied as follows:

Code	Size (mL)	NDC	Product Name
6E1023	500	0338-6315-03	2.5% Dextrose and 0.45% Sodium Chloride
6E1024	1000	0338-6315-04	Injection, USP

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100, 16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091, 16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055, 17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065, 17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029, 19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

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6E1092	250	0338-6310-02	5% Dextrose and 0.2% Sodium Chloride
6E1093	500	0338-6310-03	Injection, USP
6E1094	1000	0338-6310-04	
6E1082	250	0338-6309-02	5% Dextrose and 0.33% Sodium Chloride
6E1083	500	0338-6309-03	Injection, USP
6E1084	1000	0338-6309-04	
6E1072	250	0338-6308-02	5% Dextrose and 0.45% Sodium Chloride
6E1073	500	0338-6308-03	Injection, USP
6E1074	1000	0338-6308-04	
6E1062	250	0338-6305-02	5% Dextrose and 0.9% Sodium Chloride
6E1063	500	0338-6305-03	Injection, USP
6E1064	1000	0338-6305-04	
6E1163	500	0338-6314-03	10% Dextrose and 0.9% Sodium Chloride
6E1164	1000	0338-6314-04	Injection, USP

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure up to 40°C does not adversely affect the product.

Directions for Use of AVIVA plastic container

To Open

Tear overwrap down side at slit and remove solution container. Moisture and some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

Caution: Do not use plastic containers in series connections.

Caution: Use only with a non-vented set or a vented set with the vent closed.

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Additives may be incompatible.

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100,
16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091,
16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055,
17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065,
17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029,
19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

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To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

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Sodium Lactate Injection, USP (M/6 Sodium Lactate) in AVIVA Plastic Container

Description

Sodium Lactate Injection, USP (M/6 Sodium Lactate) is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment and caloric supply in a single dose container for intravenous administration. It contains no antimicrobial agents. The pH may have been adjusted with lactic acid. Composition, osmolarity, pH, ionic concentration and caloric content are shown in Table 1.

Table 1

	Size (mL)	Composition (g/L)	*Osmolarity (mOsmol/L) (calc)	pH	Ionic Concentration (mEq/L)		Caloric Content (kcal/L)
		Sodium Lactate (C ₃ H ₅ NaO ₃)			Sodium	Lactate	
Sodium Lactate Injection, USP (M/6 Sodium Lactate)	500	18.7	334	6.5 (6.0 to 7.3)	167	167	54
	1000						

*Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L.
Administration of substantially hypertonic solutions (≥ 600 mOsmol/L) may cause vein damage.

The flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of paclitaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

The suitability of the container materials has been established through biological evaluations, which have shown the container passes Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system.

The flexible container is a closed system, and air is prefilled in the container to facilitate drainage. The container does not require entry of external air during administration.

The container has two ports: one is the administration outlet port for attachment of an intravenous administration set and the other port has a medication site for addition of supplemental medication

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100, 16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091, 16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055, 17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065, 17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029, 19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

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(See Directions for Use). The primary function of the overwrap is to protect the container from the physical environment.

Clinical Pharmacology

Sodium Lactate Injection, USP has value as a source of water, electrolytes, and calories. It is capable of inducing diuresis depending on the clinical condition of the patient.

Sodium Lactate Injection, USP produces a metabolic alkalizing effect. Lactate ions are metabolized ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

Indications and Usage

Sodium Lactate Injection, USP is indicated as a source of water, electrolytes, and calories or as an alkalizing agent.

Contraindications

None known

Warnings

Sodium Lactate Injection, USP should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

Sodium Lactate Injection, USP should be used with great care in patients with metabolic or respiratory alkalosis. The administration of lactate ions should be done with great care in those conditions in which there is an increased level or an impaired utilization of these ions, such as severe hepatic insufficiency.

The intravenous administration of these injections can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injection. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection.

Excessive administration of Sodium Lactate Injection, USP may result in significant hypokalemia.

In patients with diminished renal function, administration of Sodium Lactate Injection, USP may result in sodium retention.

Sodium Lactate Injection, USP is not for use in the treatment of lactic acidosis.

Precautions

General

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100, 16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091, 16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055, 17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065, 17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029, 19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

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Do not connect flexible plastic containers of intravenous solutions in series, i.e., do not piggyback connections. Such use could result in air embolism due to residual air being drawn from one container before administration of the fluid from a secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

Laboratory Tests

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

Drug Interactions

Caution must be exercised in the administration of Sodium Lactate Injection, USP (M/6 Sodium Lactate) to patients receiving corticosteroids or corticotropin.

Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with Sodium Lactate Injection, USP (M/6 Sodium Lactate).

Carcinogenesis, mutagenesis, impairment of fertility

Studies with Sodium Lactate Injection, USP have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy: Teratogenic Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with Sodium Lactate Injection, USP. It is also not known whether Sodium Lactate Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium Lactate Injection, USP should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Studies have not been conducted to evaluate the effects of Sodium Lactate Injection, USP (M/6 Sodium Lactate) on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Sodium Lactate Injection, USP is administered to a nursing mother.

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Pediatric Use

Safety and effectiveness of Sodium Lactate Injection, USP in pediatric patients have not been established by adequate and well controlled trials, however, the use of sodium lactate solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

Geriatric Use

Clinical studies of Sodium Lactate Injection, USP did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Adverse Reactions

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

Dosage and Administration

As directed by a physician. Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Use of a final filter is recommended during administration of all parenteral solutions, where possible. Do not administer unless solution is clear and seal is intact.

All injections in AVIVA plastic containers are intended for intravenous administration using sterile equipment.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

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How Supplied

Sodium Lactate Injection, USP (M/6 Sodium Lactate) in AVIVA plastic container is available as follows:

Code	Size (mL)	NDC
6E1803	500	0338-6311-03
6E1804	1000	0338-6311-04

EXPOSURE OF PHARMACEUTICAL PRODUCTS TO HEAT SHOULD BE MINIMIZED. AVOID EXCESSIVE HEAT. IT IS RECOMMENDED THE PRODUCT BE STORED AT ROOM TEMPERATURE (25°C); BRIEF EXPOSURE UP TO 40°C DOES NOT ADVERSELY AFFECT THE PRODUCT.

Directions for Use of AVIVA Plastic Container

To Open

Tear overwrap down side at slit and remove solution container. Moisture and some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

Caution: Do not use plastic containers in series connections.

Caution: Use only with a non-vented set or a vented set with the vent closed.

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Additives may be incompatible.

To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.

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16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091,
16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055,
17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065,
17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029,
19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

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5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

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Ringer's Injection, USP in AVIVA Plastic Container

Table 1

	Size (mL)	Composition (g/L)			Osmolarity (mOsmol/L) (calc)	pH	Ionic Concentration (mEq/L)			
		Sodium Chloride, USP (NaCl)	Calcium Chloride, USP (CaCl ₂ ·2H ₂ O)	Potassium Chloride, USP (KCl)			Sodium	Potassium	Calcium	Chloride
Ringer's Injection, USP	500	8.6	0.33	0.3	309	5.5 (5.0 to 7.5)	147.5	4	4.5	156
	1000									

Description

Ringer's Injection, USP is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment in single dose containers for intravenous administration. It contains no antimicrobial agents. The pH may have been adjusted with sodium hydroxide. Composition, osmolarity, pH and ionic concentration are shown in Table 1.

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100, 16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091, 16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055, 17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065, 17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029, 19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022
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The flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of paclitaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

The suitability of the container materials has been established through biological evaluations, which have shown the container passes Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system. The flexible container is a closed system, and air is pre-filled in the container to facilitate drainage. The container does not require entry of external air during administration.

The container has two ports: one is the administration outlet port for attachment of an intravenous administration set and the other port has a medication site for addition of supplemental medication (See Directions for Use). The primary function of the overwrap is to protect the container from the physical environment.

Clinical Pharmacology

Ringer's Injection, USP has value as a source of water and electrolytes. It is capable of inducing diuresis depending on the clinical condition of the patient.

Indications and Usage

Ringer's Injection, USP is indicated as a source of water and electrolytes.

Contraindications

None known

Warnings

Ringer's Injection, USP should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

Ringer's Injection, USP should be used with great care, if at all, in patients with hyperkalemia, severe renal failure, and in conditions in which potassium retention is present.

Ringer's Injection, USP should not be administered simultaneously with blood through the same administration set because of the likelihood of coagulation.

The intravenous administration of Ringer's Injection, USP can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary

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edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injection. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection.

In patients with diminished renal function, administration of Ringer's Injection, USP may result in sodium or potassium retention.

Precautions

General

Do not connect flexible plastic containers of intravenous solutions in series, i.e., do not piggyback connections. Such use could result in air embolism due to residual air being drawn from one container before administration of the fluid from a secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

Laboratory Tests

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

Drug Interactions

Caution must be exercised in the administration of Ringer's Injection, USP to patients receiving corticosteroids or corticotropin.

Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with Ringer's Injection, USP.

Carcinogenesis, mutagenesis, impairment of fertility

Studies with Ringer's Injection, USP have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy: Teratogenic Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with Ringer's Injection, USP. It is also not known whether Ringer's Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Ringer's Injection, USP should be given to a pregnant woman only if clearly needed.

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Labor and Delivery

Studies have not been conducted to evaluate the effects of Ringer's Injection, USP on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Ringer's Injection, USP is administered to a nursing woman.

Pediatric Use

Safety and effectiveness of Ringer's Injection, USP in pediatric patients have not been established by adequate and well controlled trials, however, the use of electrolyte solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

Geriatric Use

Clinical studies of Ringer's Injection, USP did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Adverse Reactions

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

Dosage and Administration

As directed by a physician. Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Do not administer unless solution is clear and seal is intact.

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100, 16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091, 16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055, 17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065, 17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029, 19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

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All injections in AVIVA plastic containers are intended for intravenous administration using sterile equipment.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

How Supplied

Ringer's Injection, USP in AVIVA plastic container is available as follows:

Code	Size (mL)	NDC
6E2303	500	NDC 0338-6312-03
6E2304	1000	NDC 0338-6312-04

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure to up to 40°C does not adversely affect the product.

Directions for Use of AVIVA Plastic Container

To Open

Tear overwrap down side at slit and remove solution container. Moisture and some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

Caution: Do not use plastic containers in series connections.

Caution: Use only with a non-vented set or a vented set with the vent closed.

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Additives may be incompatible.

To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.

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16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091,
16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055,
17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065,
17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029,
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3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in-use position and continue administration.

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Ringer's Injection, USP in AVIVA Plastic Container

Description

Ringer's Injection, USP is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment in single dose containers for intravenous administration. It contains no antimicrobial agents. The pH may have been adjusted with sodium hydroxide. Composition, osmolarity, pH and ionic concentration are shown in Table 1.

Table 1

	Size (mL)	Composition (g/L)			Osmolarity (mOsmol/L) (calc)	pH	Ionic Concentration (mEq/L)			
		Sodium Chloride, USP (NaCl)	Calcium Chloride, USP (CaCl ₂ ·2H ₂ O)	Potassium Chloride, USP (KCl)			Sodium	Potassium	Calcium	Chloride
Ringer's Injection, USP	500	8.6	0.33	0.3	309	5.5 (5.0 to 7.5)	147.5	4	4.5	156
	1000									

The flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of paclitaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

The suitability of the container materials has been established through biological evaluations, which have shown the container passes Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system.

The flexible container is a closed system, and air is prefilled in the container to facilitate drainage. The container does not require entry of external air during administration.

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The container has two ports: one is the administration outlet port for attachment of an intravenous administration set and the other port has a medication site for addition of supplemental medication (See Directions for Use). The primary function of the overwrap is to protect the container from the physical environment.

Clinical Pharmacology

Ringer's Injection, USP has value as a source of water and electrolytes. It is capable of inducing diuresis depending on the clinical condition of the patient.

Indications and Usage

Ringer's Injection, USP is indicated as a source of water and electrolytes.

Contraindications

None known

Warnings

Ringer's Injection, USP should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

Ringer's Injection, USP should be used with great care, if at all, in patients with hyperkalemia, severe renal failure, and in conditions in which potassium retention is present.

Ringer's Injection, USP should not be administered simultaneously with blood through the same administration set because of the likelihood of coagulation.

The intravenous administration of Ringer's Injection, USP can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injection. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection.

In patients with diminished renal function, administration of Ringer's Injection, USP may result in sodium or potassium retention.

Precautions

General

Do not connect flexible plastic containers of intravenous solutions in series, i.e., do not piggyback connections. Such use could result in air embolism due to residual air being drawn from one container before administration of the fluid from a secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100, 16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091, 16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055, 17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065, 17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029, 19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

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Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

Laboratory Tests

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

Drug Interactions

Caution must be exercised in the administration of Ringer's Injection, USP to patients receiving corticosteroids or corticotropin.

Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with Ringer's Injection, USP.

Carcinogenesis, mutagenesis, impairment of fertility

Studies with Ringer's Injection, USP have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy: Teratogenic Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with Ringer's Injection, USP. It is also not known whether Ringer's Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Ringer's Injection, USP should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Studies have not been conducted to evaluate the effects of Ringer's Injection, USP on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Ringer's Injection, USP is administered to a nursing woman.

Pediatric Use

Safety and effectiveness of Ringer's Injection, USP in pediatric patients have not been established by adequate and well controlled trials, however, the use of electrolyte solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

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Geriatric Use

Clinical studies of Ringer's Injection, USP did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Adverse Reactions

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

Dosage and Administration

As directed by a physician. Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Do not administer unless solution is clear and seal is intact.

All injections in AVIVA plastic containers are intended for intravenous administration using sterile equipment.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

How Supplied

Ringer's Injection, USP in AVIVA plastic container is available as follows:

Code	Size (mL)	NDC
6E2303	500	NDC 0338-6312-03
6E2304	1000	NDC 0338-6312-04

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100,
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16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055,
17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065,
17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029,
19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

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Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure to up to 40°C does not adversely affect the product.

Directions for Use of AVIVA Plastic Container

To Open

Tear overwrap down side at slit and remove solution container. Moisture and some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

Caution: Do not use plastic containers in series connections.

Caution: Use only with a non-vented set or a vented set with the vent closed.

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Additives may be incompatible.

To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in-use position and continue administration.

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16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055,
17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065,
17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029,
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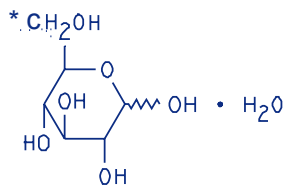
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Ringer's and 5% Dextrose Injection, USP in AVIVA Plastic Container

Description

Ringer's and 5% Dextrose Injection, USP is sterile, nonpyrogenic solution for fluid and electrolyte replenishment and caloric supply in a single dose container for intravenous administration. Each 100 mL contains 5 g Dextrose Hydrous, USP*; 860 mg of Sodium Chloride, USP (NaCl); 33 mg of Calcium Chloride, USP (CaCl₂•2H₂O); and 30 mg of Potassium Chloride, USP (KCl). It contains no antimicrobial agents. The pH is 4.0 (3.5 to 6.5).



D-Glucopyranose monohydrate

Ringer's and 5% Dextrose Injection, USP administered intravenously has value as a source of water, electrolytes, and calories. One liter has an ionic concentration of 147.5 mEq sodium, 4.5 mEq calcium, 4 mEq potassium, and 156 mEq chloride. The osmolarity is 561 mOsmol/L (calc). Normal physiologic range is approximately 280 to 310 mOsmol/L. Administration of substantially hypertonic solutions may cause vein damage. The caloric content is 170 kcal/L.

The flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of paclitaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

The suitability of the container materials has been established through biological evaluations, which have shown the container passes Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system.

The flexible container is a closed system, and air is pre-filled in the container to facilitate drainage. The container does not require entry of external air during administration.

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The container has two ports: one is the administration outlet port for attachment of an intravenous administration set and the other port has a medication site for addition of supplemental medication (See Directions for Use). The primary function of the overwrap is to protect the container from the physical environment.

Clinical Pharmacology

Ringer's and 5% Dextrose Injection, USP has value as a source of water, electrolytes, and calories. It is capable of inducing diuresis depending on the clinical condition of the patient.

Indications and Usage

Ringer's and 5% Dextrose Injection, USP is indicated as a source of water, electrolytes and calories.

Contraindications

Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn products.

Warnings

Ringer's and 5% Dextrose Injection, USP should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

Ringer's and 5% Dextrose Injection, USP should be used with great care, if at all, in patients with hyperkalemia, severe renal failure, and in conditions in which potassium retention is present.

Ringer's and 5% Dextrose Injection, USP should not be administered simultaneously with blood through the same administration set because of the likelihood of coagulation.

The intravenous administration of Ringer's and 5% Dextrose Injection, USP can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injection. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection.

In patients with diminished renal function, administration of Ringer's and 5% Dextrose Injection, USP may result in sodium or potassium retention.

Precautions

General

Do not connect flexible plastic containers of intravenous solutions in series, i.e., do not piggyback connections. Such use could result in air embolism due to residual air being drawn from one container before administration of the fluid from a secondary container is completed.

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Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

Ringer's and 5% Dextrose Injection, USP should be used with caution in patients with overt or subclinical diabetes mellitus.

Laboratory Tests

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

Drug Interactions

Caution must be exercised in the administration of Ringer's and 5% Dextrose Injection, USP to patients receiving corticosteroids or corticotropin.

Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with Ringer's and 5% Dextrose Injection, USP.

Carcinogenesis, mutagenesis, impairment of fertility

Studies with Ringer's and 5% Dextrose Injection, USP have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy: Teratogenic Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with Ringer's and 5% Dextrose Injection, USP. It is also not known whether Ringer's and 5% Dextrose Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Ringer's and 5% Dextrose Injection, USP should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Studies have not been conducted to evaluate the effects of Ringer's and 5% Dextrose Injection, USP on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Ringer's and 5% Dextrose Injection, USP is administered to a nursing woman.

Pediatric Use

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Safety and effectiveness of Ringer's and 5% Dextrose Injection, USP in pediatric patients have not been established by adequate and well controlled trials, however, the use of ringer's and dextrose solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

In very low birth weight infants, excessive or rapid administration of dextrose injection may result in increased serum osmolality and possible hemorrhage.

Geriatric Use

Clinical studies of Ringer's and 5% Dextrose Injection, USP did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in the responses between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Adverse Reactions

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation, and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

Dosage and Administration

As directed by a physician. Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Do not administer unless solution is clear and seal is intact.

All injections in AVIVA plastic containers are intended for intravenous administration using sterile equipment.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment

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of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

How Supplied

Ringer's and 5% Dextrose Injection, USP in AVIVA plastic containers is available as shown below:

Code	Size (mL)	NDC
6E2064	1000	NDC 0338-6313-04
6E2063	500	NDC 0338-6313-03

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C): brief exposure up to 40°C does not adversely affect the product.

Directions for Use of AVIVA Plastic Container

To Open

Tear overwrap down side at slit and remove solution container. Moisture and some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

Caution: Do not use plastic containers in series connections.

Caution: Use only with a non-vented set or a vented set with the vent closed.

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Additives may be incompatible.

To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.

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17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029,
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4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

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Dextrose and Sodium Chloride Injection, USP in AVIVA Plastic Container

Description

Dextrose and Sodium Chloride Injection, USP is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment and caloric supply in single dose containers for intravenous administration. It contains no antimicrobial agents. Composition, osmolarity, pH, ionic concentration and caloric content are shown in Table 1.

Table 1

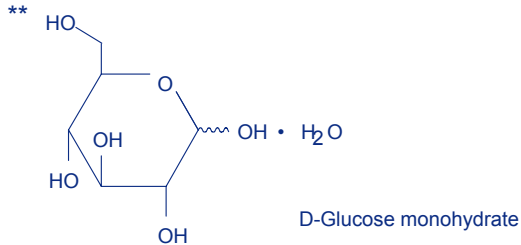
	Size (mL)	Composition (g/L)		*Osmolarity (mOsmol/L) (calc.)	pH	Ionic Concentration (mEq/L)		Caloric Content (kcal/L)
		** Dextrose Hydrous, USP	Sodium Chloride, USP (NaCl)			Sodium	Chloride	
2.5% Dextrose and 0.45% Sodium Chloride Injection, USP	500 1000	25	4.5	280	4.5 (3.2 to 6.5)	77	77	85
5% Dextrose and 0.2% Sodium Chloride Injection, USP	250 500 1000	50	2	321	4.0 (3.2 to 6.5)	34	34	170
5% Dextrose and 0.33% Sodium Chloride Injection, USP	250 500 1000	50	3.3	365	4.0 (3.2 to 6.5)	56	56	170
5% Dextrose and 0.45% Sodium Chloride Injection, USP	250 500 1000	50	4.5	406	4.0 (3.2 to 6.5)	77	77	170
5% Dextrose and 0.9% Sodium Chloride Injection, USP	250 500 1000	50	9	560	4.0 (3.2 to 6.5)	154	154	170
10% Dextrose and 0.9% Sodium Chloride Injection, USP	500 1000	100	9	813	4.0 (3.2 to 6.5)	154	154	340

*Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L.

Administration of substantially hypertonic solutions (≥ 600 mOsmol/L) may cause vein damage.

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The flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of paclitaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

The suitability of the container materials has been established through biological evaluations, which have shown the container passes Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system.

The flexible container is a closed system, and air is prefilled in the container to facilitate drainage. The container does not require entry of external air during administration.

The container has two ports: one is the administration outlet port for attachment of an intravenous administration set and the other port has a medication site for addition of supplemental medication (See Directions for Use). The primary function of the overwrap is to protect the container from the physical environment.

Clinical Pharmacology

Dextrose and Sodium Chloride Injection, USP has value as a source of water, electrolytes, and calories. It is capable of inducing diuresis depending on the clinical condition of the patient.

Indications and Usage

Dextrose and Sodium Chloride Injection, USP is indicated as a source of water, electrolytes, and calories.

Contraindications

Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn products.

Warnings

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100, 16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091, 16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055, 17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065, 17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029, 19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

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Dextrose and Sodium Chloride Injection, USP should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

Dextrose injections with low electrolyte concentrations should not be administered simultaneously with blood through the same administration set because of the possibility of pseudoagglutination or hemolysis. The container label for these injections bears the statement: Do not administer simultaneously with blood.

The intravenous administration of Dextrose and Sodium Chloride Injection, USP can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injections. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injections.

Excessive administration of Dextrose and Sodium Chloride Injection, USP may result in significant hypokalemia.

In patients with diminished renal function, administration of Dextrose and Sodium Chloride Injection, USP may result in sodium retention.

Precautions

General

Do not connect flexible plastic containers of intravenous solutions in series, i.e., do not piggyback connections. Such use could result in air embolism due to residual air being drawn from one container before administration of the fluid from a secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

Dextrose and Sodium Chloride Injection, USP should be used with caution in patients with overt or subclinical diabetes mellitus.

Laboratory Tests

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100, 16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091, 16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055, 17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065, 17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029, 19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

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Drug Interactions

Caution must be exercised in the administration of Dextrose and Sodium Chloride Injection, USP to patients receiving corticosteroids or corticotropin.

Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with Dextrose and Sodium Chloride Injection, USP.

Carcinogenesis, mutagenesis, impairment of fertility

Studies with Dextrose and Sodium Chloride Injection, USP have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy: Teratogenic Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with Dextrose and Sodium Chloride Injection, USP. It is also known whether Dextrose and Sodium Chloride Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Dextrose and Sodium Chloride Injection, USP should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Studies have not been conducted to evaluate the effects of Dextrose and Sodium Chloride Injection, USP on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Dextrose and Sodium Chloride Injection, USP is administered to a nursing mother.

Pediatric Use

Safety and effectiveness of Dextrose and Sodium Chloride Injection, USP in pediatric patients have not been established by adequate and well controlled trials, however, the use of dextrose and sodium chloride solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

In very low birth weight infants, excessive or rapid administration of dextrose injection may result in increased serum osmolality and possible hemorrhage.

Geriatric Use

Clinical studies of Dextrose and Sodium Chloride Injection, USP did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in the responses between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100, 16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091, 16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055, 17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065, 17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029, 19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

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at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Adverse Reactions

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

Dosage and Administration

As directed by a physician. Dosage is dependent upon the age, weight, and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Do not administer unless solution is clear and seal is intact.

All injections in AVIVA plastic containers are intended for intravenous administration using sterile equipment.

As reported in the literature, the dosage and constant infusion rate of intravenous dextrose must be selected with caution in pediatric patients, particularly neonates and low weight infants, because of the increased risk of hyperglycemia/hypoglycemia.

Additives may be incompatible. Complete information is not available.

Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

How Supplied

Dextrose and Sodium Chloride Injection, USP in AVIVA plastic container is supplied as follows:

Code	Size (mL)	NDC	Product Name
6E1023	500	0338-6315-03	2.5% Dextrose and 0.45% Sodium Chloride
6E1024	1000	0338-6315-04	Injection, USP

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100, 16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091, 16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055, 17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065, 17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029, 19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

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6E1092	250	0338-6310-02	5% Dextrose and 0.2% Sodium Chloride
6E1093	500	0338-6310-03	Injection, USP
6E1094	1000	0338-6310-04	
6E1082	250	0338-6309-02	5% Dextrose and 0.33% Sodium Chloride
6E1083	500	0338-6309-03	Injection, USP
6E1084	1000	0338-6309-04	
6E1072	250	0338-6308-02	5% Dextrose and 0.45% Sodium Chloride
6E1073	500	0338-6308-03	Injection, USP
6E1074	1000	0338-6308-04	
6E1062	250	0338-6305-02	5% Dextrose and 0.9% Sodium Chloride
6E1063	500	0338-6305-03	Injection, USP
6E1064	1000	0338-6305-04	
6E1163	500	0338-6314-03	10% Dextrose and 0.9% Sodium Chloride
6E1164	1000	0338-6314-04	Injection, USP

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure up to 40°C does not adversely affect the product.

Directions for Use of AVIVA plastic container

To Open

Tear overwrap down side at slit and remove solution container. Moisture and some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

Caution: Do not use plastic containers in series connections.

Caution: Use only with a non-vented set or a vented set with the vent closed.

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Additives may be incompatible.

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100,
16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091,
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To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

Baxter Healthcare Corporation

Deerfield, IL 60015 USA

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Dextrose and Sodium Chloride Injection, USP in AVIVA Plastic Container

Description

Dextrose and Sodium Chloride Injection, USP is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment and caloric supply in single dose containers for intravenous administration. It contains no antimicrobial agents. Composition, osmolarity, pH, ionic concentration and caloric content are shown in Table 1.

Table 1

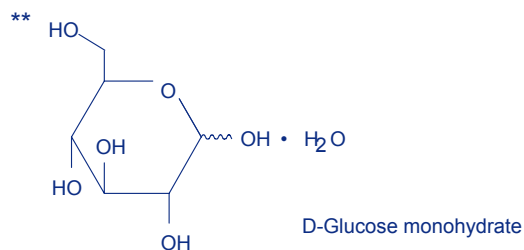
	Size (mL)	Composition (g/L)		*Osmolarity (mOsmol/L) (calc.)	pH	Ionic Concentration (mEq/L)		Caloric Content (kcal/L)
		** Dextrose Hydrous, USP	Sodium Chloride, USP (NaCl)			Sodium	Chloride	
2.5% Dextrose and 0.45% Sodium Chloride Injection, USP	500 1000	25	4.5	280	4.5 (3.2 to 6.5)	77	77	85
5% Dextrose and 0.2% Sodium Chloride Injection, USP	250 500 1000	50	2	321	4.0 (3.2 to 6.5)	34	34	170
5% Dextrose and 0.33% Sodium Chloride Injection, USP	250 500 1000	50	3.3	365	4.0 (3.2 to 6.5)	56	56	170
5% Dextrose and 0.45% Sodium Chloride Injection, USP	250 500 1000	50	4.5	406	4.0 (3.2 to 6.5)	77	77	170
5% Dextrose and 0.9% Sodium Chloride Injection, USP	250 500 1000	50	9	560	4.0 (3.2 to 6.5)	154	154	170
10% Dextrose and 0.9% Sodium Chloride Injection, USP	500 1000	100	9	813	4.0 (3.2 to 6.5)	154	154	340

*Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L.

Administration of substantially hypertonic solutions (≥ 600 mOsmol/L) may cause vein damage.

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The flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of paclitaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

The suitability of the container materials has been established through biological evaluations, which have shown the container passes Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system.

The flexible container is a closed system, and air is prefilled in the container to facilitate drainage. The container does not require entry of external air during administration.

The container has two ports: one is the administration outlet port for attachment of an intravenous administration set and the other port has a medication site for addition of supplemental medication (See Directions for Use). The primary function of the overwrap is to protect the container from the physical environment.

Clinical Pharmacology

Dextrose and Sodium Chloride Injection, USP has value as a source of water, electrolytes, and calories. It is capable of inducing diuresis depending on the clinical condition of the patient.

Indications and Usage

Dextrose and Sodium Chloride Injection, USP is indicated as a source of water, electrolytes, and calories.

Contraindications

Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn products.

Warnings

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100, 16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091, 16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055, 17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065, 17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029, 19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

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Dextrose and Sodium Chloride Injection, USP should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

Dextrose injections with low electrolyte concentrations should not be administered simultaneously with blood through the same administration set because of the possibility of pseudoagglutination or hemolysis. The container label for these injections bears the statement: Do not administer simultaneously with blood.

The intravenous administration of Dextrose and Sodium Chloride Injection, USP can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injections. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injections.

Excessive administration of Dextrose and Sodium Chloride Injection, USP may result in significant hypokalemia.

In patients with diminished renal function, administration of Dextrose and Sodium Chloride Injection, USP may result in sodium retention.

Precautions

General

Do not connect flexible plastic containers of intravenous solutions in series, i.e., do not piggyback connections. Such use could result in air embolism due to residual air being drawn from one container before administration of the fluid from a secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

Dextrose and Sodium Chloride Injection, USP should be used with caution in patients with overt or subclinical diabetes mellitus.

Laboratory Tests

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

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Drug Interactions

Caution must be exercised in the administration of Dextrose and Sodium Chloride Injection, USP to patients receiving corticosteroids or corticotropin.

Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with Dextrose and Sodium Chloride Injection, USP.

Carcinogenesis, mutagenesis, impairment of fertility

Studies with Dextrose and Sodium Chloride Injection, USP have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy: Teratogenic Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with Dextrose and Sodium Chloride Injection, USP. It is also known whether Dextrose and Sodium Chloride Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Dextrose and Sodium Chloride Injection, USP should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Studies have not been conducted to evaluate the effects of Dextrose and Sodium Chloride Injection, USP on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

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It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Dextrose and Sodium Chloride Injection, USP is administered to a nursing mother.

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Safety and effectiveness of Dextrose and Sodium Chloride Injection, USP in pediatric patients have not been established by adequate and well controlled trials, however, the use of dextrose and sodium chloride solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

In very low birth weight infants, excessive or rapid administration of dextrose injection may result in increased serum osmolality and possible hemorrhage.

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Clinical studies of Dextrose and Sodium Chloride Injection, USP did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in the responses between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting

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at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Adverse Reactions

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

Dosage and Administration

As directed by a physician. Dosage is dependent upon the age, weight, and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Do not administer unless solution is clear and seal is intact.

All injections in AVIVA plastic containers are intended for intravenous administration using sterile equipment.

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Additives may be incompatible. Complete information is not available.

Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

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6E1092	250	0338-6310-02	5% Dextrose and 0.2% Sodium Chloride
6E1093	500	0338-6310-03	Injection, USP
6E1094	1000	0338-6310-04	
6E1082	250	0338-6309-02	5% Dextrose and 0.33% Sodium Chloride
6E1083	500	0338-6309-03	Injection, USP
6E1084	1000	0338-6309-04	
6E1072	250	0338-6308-02	5% Dextrose and 0.45% Sodium Chloride
6E1073	500	0338-6308-03	Injection, USP
6E1074	1000	0338-6308-04	
6E1062	250	0338-6305-02	5% Dextrose and 0.9% Sodium Chloride
6E1063	500	0338-6305-03	Injection, USP
6E1064	1000	0338-6305-04	
6E1163	500	0338-6314-03	10% Dextrose and 0.9% Sodium Chloride
6E1164	1000	0338-6314-04	Injection, USP

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure up to 40°C does not adversely affect the product.

Directions for Use of AVIVA plastic container

To Open

Tear overwrap down side at slit and remove solution container. Moisture and some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

Caution: Do not use plastic containers in series connections.

Caution: Use only with a non-vented set or a vented set with the vent closed.

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Additives may be incompatible.

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100,
16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091,
16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055,
17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065,
17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029,
19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

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To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

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PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP)

in AVIVA Plastic Container

Description

PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) is a sterile, nonpyrogenic isotonic solution in a single dose container for intravenous administration. Each 100 mL contains 526 mg of Sodium Chloride, USP (NaCl); 502 mg of Sodium Gluconate (C₆H₁₁NaO₇); 368 mg of Sodium Acetate Trihydrate, USP (C₂H₃NaO₂•3H₂O); 37 mg of Potassium Chloride, USP (KCl); and 30 mg of Magnesium Chloride, USP (MgCl₂•6H₂O). It contains no antimicrobial agents. The pH is adjusted with hydrochloric acid. The pH is 5.5 (4.0 to 8.0).

PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) administered intravenously has value as a source of water, electrolytes, and calories. One liter has an ionic concentration of 140 mEq sodium, 5 mEq potassium, 3 mEq magnesium, 98 mEq chloride, 27 mEq acetate, and 23 mEq gluconate. The osmolarity is 294 mOsmol/L (calc). Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L. Administration of substantially hypertonic solutions may cause vein damage. The caloric content is 21 kcal/L.

The flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of paclitaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

The suitability of the container materials has been established through biological evaluations, which have shown the container passes Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system.

The flexible container is a closed system, and air is prefilled in the container to facilitate drainage. The container does not require entry of external air during administration.

The container has two ports: one is the administration outlet port for attachment of an intravenous administration set and the other port has a medication site for addition of supplemental medication (See Directions for Use). The primary function of the overwrap is to protect the container from the physical environment.

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100, 16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091, 16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055, 17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065, 17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029, 19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

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Clinical Pharmacology

PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) has value as a source of water and electrolytes. It is capable of inducing diuresis depending on the clinical condition of the patient.

PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) produces a metabolic alkalizing effect. Acetate and gluconate ions are metabolized ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

Indications and Usage

PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) is indicated as a source of water and electrolytes or as an alkalizing agent.

PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) is compatible with blood or blood components. It may be administered prior to or following the infusion of blood through the same administration set (i.e., as a priming solution), added to or infused concurrently with blood components, or used as a diluent in the transfusion of packed erythrocytes. PLASMA-LYTE 148 Injection and 0.9% Sodium Chloride Injection, USP are equally compatible with blood or blood components.

Contraindications

None known

Warnings

PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) should be used with great care, if at all, in patients with hyperkalemia, severe renal failure, and in conditions in which potassium retention is present.

PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) should be used with great care in patients with metabolic or respiratory alkalosis. The administration of acetate or gluconate ions should be done with great care in those conditions in which there is an increased level or an impaired utilization of these ions, such as severe hepatic insufficiency.

The intravenous administration of PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injection. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection.

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100, 16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091, 16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055, 17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065, 17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029, 19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022
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In patients with diminished renal function, administration of PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) may result in sodium or potassium retention.

Precautions

General

Do not connect flexible plastic containers of intravenous solutions in series, i.e., do not piggyback connections. Such use could result in air embolism due to residual air being drawn from one container before administration of the fluid from a secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) should be used with caution. Excess administration may result in metabolic alkalosis.

Laboratory Tests

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

Drug Interactions

Caution must be exercised in the administration of PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) to patients receiving corticosteroids or corticotropin.

Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP).

Carcinogenesis, mutagenesis, impairment of fertility

Studies with PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy: Teratogenic Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP). It is also not known whether PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) should be given to a pregnant woman only if clearly needed.

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100, 16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091, 16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055, 17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065, 17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029, 19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

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Labor and Delivery

Studies have not been conducted to evaluate the effects of PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) is administered to a nursing woman.

Pediatric Use

Safety and effectiveness of PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) in pediatric patients have not been established by adequate and well controlled trials, however, the use of electrolyte solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

Geriatric Use

Clinical studies of PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Adverse Reactions

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

Dosage and Administration

As directed by a physician. Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations.

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Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Do not administer unless solution is clear and seal is intact.

All injections in AVIVA plastic containers are intended for intravenous administration using sterile equipment.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

How Supplied

PLASMA-LYTE 148 Injection (Multiple Electrolytes Injection, Type 1, USP) in AVIVA plastic containers is available as shown below:

Code	Size (mL)	NDC
6E2534	1000	NDC 0338-6316-04
6E2533	500	NDC 0338-6316-03

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure up to 40°C does not adversely affect the product.

Directions for Use of AVIVA Plastic Container

To Open

Tear overwrap down side at slit and remove solution container. Moisture and some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

Caution: Do not use plastic containers in series connections.

Caution: Use only with a non-vented set or a vented set with the vent closed.

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Additives may be incompatible.

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100,
16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091,
16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055,
17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065,
17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029,
19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

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To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

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PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) in AVIVA Plastic Container

Description

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) is a sterile, nonpyrogenic isotonic solution in a single dose container for intravenous administration. Each 100 mL contains 526 mg of Sodium Chloride, USP (NaCl); 502 mg of Sodium Gluconate ($C_6H_{11}NaO_7$); 368 mg of Sodium Acetate Trihydrate, USP ($C_2H_3NaO_2 \cdot 3H_2O$); 37 mg of Potassium Chloride, USP (KCl); and 30 mg of Magnesium Chloride, USP ($MgCl_2 \cdot 6H_2O$). It contains no antimicrobial agents. The pH is adjusted with sodium hydroxide. The pH is 7.4 (6.5 to 8.0).

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) administered intravenously has value as a source of water, electrolytes, and calories. One liter has an ionic concentration of 140 mEq sodium, 5 mEq potassium, 3 mEq magnesium, 98 mEq chloride, 27 mEq acetate, and 23 mEq gluconate. The osmolarity is 294 mOsmol/L (calc). Normal physiologic osmolarity range is 280 to 310 mOsmol/L. Administration of substantially hypertonic solutions may cause vein damage. The caloric content is 21 kcal/L.

The flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of paclitaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

The suitability of the container materials has been established through biological evaluations, which have shown the container passes Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system.

The flexible container is a closed system, and air is prefilled in the container to facilitate drainage. The container does not require entry of external air during administration.

The container has two ports: one is the administration outlet port for attachment of an intravenous administration set and the other port has a medication site for addition of supplemental medication (See Directions for Use). The primary function of the overwrap is to protect the container from the physical environment.

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100, 16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091, 16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055, 17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065, 17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029, 19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

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Clinical Pharmacology

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) has value as a source of water and electrolytes. It is capable of inducing diuresis depending on the clinical condition of the patient.

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) produces a metabolic alkalinizing effect. Acetate and gluconate ions are metabolized ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

Indications and Usage

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) is indicated as a source of water and electrolytes or as an alkalinizing agent.

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) is compatible with blood or blood components. It may be administered prior to or following the infusion of blood through the same administration set (i.e., as a priming solution), added to or infused concurrently with blood components, or used as a diluent in the transfusion of packed erythrocytes. PLASMA-LYTE A Injection and 0.9% Sodium Chloride Injection, USP are equally compatible with blood or blood components.

Contraindications

None known

Warnings

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) should be used with great care, if at all, in patients with hyperkalemia, severe renal failure, and in conditions in which potassium retention is present.

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) should be used with great care in patients with metabolic or respiratory alkalosis. The administration of acetate or gluconate ions should be done with great care in those conditions in which there is an increased level or an impaired utilization of these ions, such as severe hepatic insufficiency.

The intravenous administration of PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injection. The risk of solute

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100, 16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091, 16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055, 17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065, 17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029, 19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

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overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection.

In patients with diminished renal function, administration of PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) may result in sodium or potassium retention.

Precautions

General

Do not connect flexible plastic containers of intravenous solutions in series, i.e., do not piggyback connections. Such use could result in air embolism due to residual air being drawn from one container before administration of the fluid from a secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) should be used with caution. Excess administration may result in metabolic alkalosis.

Laboratory Tests

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

Drug Interactions

Caution must be exercised in the administration of PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) to patients receiving corticosteroids or corticotropin.

Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP).

Carcinogenesis, mutagenesis, impairment of fertility

Studies with PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy: Teratogenic Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP). It is also not known whether PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. PLASMA-LYTE

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A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Studies have not been conducted to evaluate the effects of PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) is administered to a nursing woman.

Pediatric Use

Safety and effectiveness of PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) in pediatric patients have not been established by adequate and well controlled trials, however, the use of electrolyte solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

Geriatric Use

Clinical studies of PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Adverse Reactions

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation, and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

Dosage and Administration

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100, 16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091, 16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055, 17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065, 17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029, 19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

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As directed by a physician. Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Do not administer unless solution is clear and seal is intact.

All injections in AVIVA plastic containers are intended for intravenous administration using sterile equipment.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

How Supplied

PLASMA-LYTE A Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) in AVIVA plastic containers is available as shown below:

Code	Size (mL)	NDC
6E2544	1000	NDC 0338-6317-04
6E2543	500	NDC 0338-6317-03

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure up to 40°C does not adversely affect the product.

Directions for Use of AVIVA Plastic Container

To Open

Tear overwrap down side at slit and remove solution container. Moisture and some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

Caution: Do not use plastic containers in series connections.

Caution: Use only with a non-vented set or a vented set with the vent closed.

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100,
16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091,
16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055,
17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065,
17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029,
19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

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To Add Medication

Additives may be incompatible.

To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

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Deerfield, IL 60015 USA

Printed in USA

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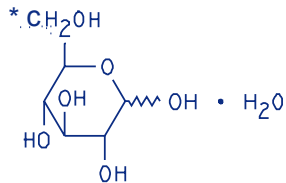
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PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) in AVIVA Plastic Container

Description

PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment and caloric supply in a single dose container for intravenous administration. Each 100 mL contains 5 g Dextrose Hydrous, USP*, 234 mg Sodium Chloride, USP (NaCl); 128 mg Potassium Acetate, USP (C₂H₃KO₂); and 32 mg Magnesium Acetate, Tetrahydrate (C₄H₆MgO₄•4H₂O). It contains no antimicrobial agents. pH 5.0 (4.0 to 6.5). The pH is adjusted with hydrochloric acid.



D-Glucopyranose monohydrate

PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) administered intravenously has value as a source of water, electrolytes, and calories. One liter has an ionic concentration of 40 mEq sodium, 13 mEq potassium, 3 mEq magnesium, 40 mEq chloride, and 16 mEq acetate. The osmolarity is 363 mOsmol/L (calc). Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L. Administration of substantially hypertonic solutions (≥ 600 mOsmol/L) may cause vein damage. The caloric content is 170 kcal/L.

The flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of paclitaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100, 16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091, 16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055, 17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065, 17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029, 19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

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The suitability of the container materials has been established through biological evaluations, which have shown the container passes Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system.

The flexible container is a closed system, and air is prefilled in the container to facilitate drainage. The container does not require entry of external air during administration.

The container has two ports: one is the administration outlet port for attachment of an intravenous administration set and the other port has a medication site for addition of supplemental medication (See Directions for Use). The primary function of the overwrap is to protect the container from the physical environment.

Clinical Pharmacology

PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) has value as a source of water, electrolytes, and calories. It is capable of inducing diuresis depending on the clinical condition of the patient.

PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) produces a metabolic alkalinizing effect. Acetate ions are metabolized ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

Indications and Usage

PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) is indicated as a source of water, electrolytes, and calories or as an alkalinizing agent.

Contraindications

Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn products.

Warnings

PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be used with great care, if at all, in patients with hyperkalemia, severe renal failure, and in conditions in which potassium retention is present.

PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be used with great care in patients with metabolic or respiratory alkalosis. The administration of acetate ions should be done with great care in those conditions in which there is an increased level or an impaired utilization of these ions, such as severe hepatic insufficiency.

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100, 16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091, 16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055, 17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065, 17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029, 19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

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PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should not be administered simultaneously with blood through the same administration set because of the possibility of pseudoagglutination or hemolysis.

The intravenous administration of PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injection. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection.

In patients with diminished renal function, administration of PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) may result in sodium or potassium retention.

Precautions

General

Do not connect flexible plastic containers of intravenous solutions in series, i.e., do not piggyback connections. Such use could result in air embolism due to residual air being drawn from one container before administration of the fluid from a secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be used with caution. Excess administration may result in metabolic alkalosis.

PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be used with caution in patients with overt or subclinical diabetes mellitus.

Laboratory Tests

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

Drug Interactions

Caution must be exercised in the administration of PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) to patients receiving corticosteroids or corticotropin.

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100, 16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091, 16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055, 17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065, 17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029, 19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

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Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP).

Carcinogenesis, mutagenesis, impairment of fertility

Studies with PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy: Teratogenic Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP). It is also not known whether PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Studies have not been conducted to evaluate the effects of PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) is administered to a nursing mother.

Pediatric Use

Safety and effectiveness of PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) in pediatric patients have not been established by adequate and well controlled trials, however, the use of plasmalyte and dextrose solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

In very low birth weight infants, excessive or rapid administration of dextrose injection may result in increased serum osmolality and possible hemorrhage.

Geriatric Use

Clinical studies of PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100, 16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091, 16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055, 17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065, 17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029, 19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

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selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Adverse Reactions

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation, and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

Dosage and Administration

As directed by a physician. Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

Do not administer unless solution is clear and seal is intact.

All injections in AVIVA plastic containers are intended for intravenous administration using sterile equipment.

As reported in the literature, the dosage and constant infusion rate of intravenous dextrose must be selected with caution in pediatric patients, particularly neonates and low weight infants, because of the increased risk of hyperglycemia/hypoglycemia.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

How Supplied

PLASMA-LYTE 56 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) in AVIVA plastic containers is available as shown below:

<u>Code</u>	<u>Size (mL)</u>	<u>NDC</u>
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NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100, 16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091, 16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055, 17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065, 17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029, 19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

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6E2573	500	NDC 0338-6318-03
6E2574	1000	NDC 0338-6318-04

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure up to 40°C does not adversely affect the product.

Directions for Use of AVIVA Plastic Container

To Open

Tear overwrap down side at slit and remove solution container. Moisture and some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

Caution: Do not use plastic containers in series connections.

Caution: Use only with a non-vented set or a vented set with the vent closed.

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Additives may be incompatible.

To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100,
16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091,
16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055,
17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065,
17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029,
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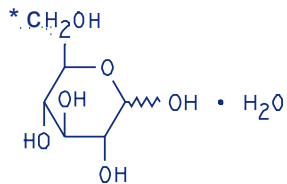
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PLASMA-LYTE M and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 2, USP) in AVIVA Plastic Container

Description

PLASMA-LYTE M and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 2, USP) is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment and caloric supply in a single dose container for intravenous administration. Each 100 mL contains 5 g Dextrose Hydrous, USP*, 161 mg Sodium Acetate Trihydrate, USP ($C_2H_3NaO_2 \cdot 3H_2O$); 138 mg Sodium Lactate ($C_3H_5NaO_3$), 119 mg Potassium Chloride, USP (KCl), 94 mg Sodium Chloride, USP (NaCl), 37 mg Calcium Chloride, USP ($CaCl_2 \cdot 2H_2O$), and 30 mg Magnesium Chloride, USP ($MgCl_2 \cdot 6H_2O$). It contains no antimicrobial agents. The pH is 5.0 (4.0 to 6.5). The pH is adjusted with hydrochloric acid.



D-Glucopyranose monohydrate

PLASMA-LYTE M and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 2, USP) administered intravenously has value as a source of water, electrolytes, and calories. One liter has an ionic concentration of 40 mEq sodium, 16 mEq potassium, 5 mEq calcium, 3 mEq magnesium, 40 mEq chloride, 12 mEq acetate, and 12 mEq lactate. The osmolarity is 377 mOsmol/L (calc). Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L. Administration of substantially hypertonic solutions (≥ 600 mOsmol/L) may cause vein damage. The caloric content is 180 kcal/L.

The flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of paclitaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100, 16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091, 16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055, 17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065, 17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029, 19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

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The suitability of the container materials has been established through biological evaluations, which have shown the container passes Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system.

The flexible container is a closed system, and air is prefilled in the container to facilitate drainage. The container does not require entry of external air during administration.

The container has two ports: one is the administration outlet port for attachment of an intravenous administration set and the other port has a medication site for addition of supplemental medication (See Directions for Use). The primary function of the overwrap is to protect the container from the physical environment.

Clinical Pharmacology

PLASMA-LYTE M and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 2, USP) has value as a source of water, electrolytes, and calories. It is capable of inducing diuresis depending on the clinical condition of the patient.

PLASMA-LYTE M and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 2, USP) produces a metabolic alkalinizing effect. Acetate and lactate ions are metabolized ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

Indications and Usage

PLASMA-LYTE M and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 2, USP) is indicated as a source of water, electrolytes, and calories or as an alkalinizing agent.

Contraindications

Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn products.

Warnings

PLASMA-LYTE M and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 2, USP) should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

PLASMA-LYTE M and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 2, USP) should be used with great care, if at all, in patients with hyperkalemia, severe renal failure, and in conditions in which potassium retention is present.

PLASMA-LYTE M and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 2, USP) should be used with great care in patients with metabolic or respiratory alkalosis. The

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administration of lactate or acetate ions should be done with great care in those conditions in which there is an increased level or an impaired utilization of these ions, such as severe hepatic insufficiency.

PLASMA-LYTE M and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 2, USP) should not be administered simultaneously with blood through the same administration set because of the likelihood of coagulation.

The intravenous administration of PLASMA-LYTE M and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 2, USP) can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injection. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection.

In patients with diminished renal function, administration of PLASMA-LYTE M and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 2, USP) containing sodium or potassium ions may result in sodium or potassium retention.

PLASMA-LYTE M and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 2, USP) is not for use in the treatment of lactic acidosis.

Precautions

General

Do not connect flexible plastic containers of intravenous solutions in series, i.e., do not piggyback connections. Such use could result in air embolism due to residual air being drawn from one container before administration of the fluid from a secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

PLASMA-LYTE M and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 2, USP) should be used with caution. Excess administration may result in metabolic alkalosis.

PLASMA-LYTE M and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 2, USP) should be used with caution in patients with overt or subclinical diabetes mellitus.

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Laboratory Tests

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

Drug Interactions

Caution must be exercised in the administration of PLASMA-LYTE M and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 2, USP) to patients receiving corticosteroids or corticotropin.

Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with PLASMA-LYTE M and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 2, USP).

Carcinogenesis, mutagenesis, impairment of fertility

Studies with PLASMA-LYTE M and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 2, USP) have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy: Teratogenic Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with PLASMA-LYTE M and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 2, USP). It is also not known whether PLASMA-LYTE M and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 2, USP) can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. PLASMA-LYTE M and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 2, USP) should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Studies have not been conducted to evaluate the effects of PLASMA-LYTE M and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 2, USP) on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when PLASMA-LYTE M and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 2, USP) is administered to a nursing mother.

Pediatric Use

Safety and effectiveness of PLASMA-LYTE M and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 2, USP) in pediatric patients have not been established by adequate and well controlled trials, however, the use of plasmalyte and dextrose solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

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In very low birth weight infants, excessive or rapid administration of dextrose injection may result in increased serum osmolality and possible hemorrhage.

Geriatric Use

Clinical studies of PLASMA-LYTE M and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 2, USP) did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Adverse Reactions

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation, and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

Dosage and Administration

As directed by a physician. Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Do not administer unless solution is clear and seal is intact.

All injections in AVIVA plastic containers are intended for intravenous administration using sterile equipment.

As reported in the literature, the dosage and constant infusion rate of intravenous dextrose must be selected with caution in pediatric patients, particularly neonates and low weight infants, because of the increased risk of hyperglycemia/hypoglycemia.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment

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of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

How Supplied

PLASMA-LYTE M and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 2, USP) in AVIVA plastic containers is available as shown below:

Size (mL)	Code	NDC
1000	6E2564	NDC 0338-6319-04
500	6E2563	NDC 0338-6319-03

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure up to 40°C does not adversely affect the product.

Directions for Use of AVIVA Plastic Container

To Open

Tear overwrap down side at slit and remove solution container. Moisture and some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

Caution: Do not use plastic containers in series connections.

Caution: Use only with a non-vented set or a vented set with the vent closed.

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Additives may be incompatible.

To add medication before solution administration

1. Prepare medication site.
 2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

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16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091,
16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055,
17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065,
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1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

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PLASMA-LYTE R INJECTION (Multiple Electrolytes Injection, Type 2, USP) in AVIVA Plastic Container

Description

PLASMA-LYTE R Injection (Multiple Electrolytes Injection, Type 2, USP) is a sterile, nonpyrogenic isotonic solution in a single dose container for intravenous administration. Each 100 mL contains 640 mg of Sodium Acetate Trihydrate, USP ($C_2H_3NaO_2 \cdot 3H_2O$); 496 mg of Sodium Chloride, USP (NaCl); 89.6 mg of Sodium Lactate ($C_3H_5NaO_3$); 74.6 mg of Potassium Chloride, USP (KCl); 36.8 mg of Calcium Chloride, USP ($CaCl_2 \cdot 2H_2O$); and 30.5 mg of Magnesium Chloride, USP ($MgCl_2 \cdot 6H_2O$). It contains no antimicrobial agents. The pH is adjusted with hydrochloric acid. The pH is 5.5 (4.0 to 8.0).

PLASMA-LYTE R Injection (Multiple Electrolytes Injection, Type 2, USP) administered intravenously has value as a source of water, electrolytes, and calories. One liter has an ionic concentration of 140 mEq sodium, 10 mEq potassium, 5 mEq calcium, 3 mEq magnesium, 103 mEq chloride, 47 mEq acetate, and 8 mEq lactate. The osmolarity is 312 mOsmol/L (calc). Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L. Administration of substantially hypertonic solutions may cause vein damage. The caloric content is 11 kcal/L.

The flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of paclitaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

The suitability of the container materials has been established through biological evaluations, which have shown the container passes Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system.

The flexible container is a closed system, and air is prefilled in the container to facilitate drainage. The container does not require entry of external air during administration.

The container has two ports: one is the administration outlet port for attachment of an intravenous administration set and the other port has a medication site for addition of supplemental medication (See Directions for Use). The primary function of the overwrap is to protect the container from the physical environment.

Clinical Pharmacology

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PLASMA-LYTE R Injection (Multiple Electrolytes Injection, Type 2, USP) has value as a source of water and electrolytes. It is capable of inducing diuresis depending on the clinical condition of the patient.

PLASMA-LYTE R Injection (Multiple Electrolytes Injection, Type 2, USP) produces a metabolic alkalinizing effect. Acetate and lactate ions are metabolized ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

Indications and Usage

PLASMA-LYTE R Injection (Multiple Electrolytes Injection, Type 2, USP) is indicated as a source of water and electrolytes or as an alkalinizing agent.

Contraindications

None known

Warnings

PLASMA-LYTE R Injection (Multiple Electrolytes Injection, Type 2, USP) should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency and in clinical states in which there exists edema with sodium retention.

PLASMA-LYTE R Injection (Multiple Electrolytes Injection, Type 2, USP) should be used with great care, if at all, in patients with hyperkalemia, severe renal failure and in conditions in which potassium retention is present.

PLASMA-LYTE R Injection (Multiple Electrolytes Injection, Type 2, USP) should be used with great care in patients with metabolic or respiratory alkalosis. The administration of lactate or acetate ions should be done with great care in those conditions in which there is an increased level or an impaired utilization of these ions, such as severe hepatic insufficiency.

PLASMA-LYTE R Injection (Multiple Electrolytes Injection, Type 2, USP) should not be administered simultaneously with blood through the same administration set because of the likelihood of coagulation.

The intravenous administration of PLASMA-LYTE R Injection (Multiple Electrolytes Injection, Type 2, USP) can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injection. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection.

In patients with diminished renal function, administration of PLASMA-LYTE R Injection (Multiple Electrolytes Injection, Type 2, USP) may result in sodium or potassium retention. PLASMA-LYTE R

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Injection (Multiple Electrolytes Injection, Type 2, USP) is not for use in the treatment of lactic acidosis.

Precautions

General

Do not connect flexible plastic containers of intravenous solutions in series, i.e., do not piggyback connections. Such use could result in air embolism due to residual air being drawn from one container before administration of the fluid from a secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

PLASMA-LYTE R Injection (Multiple Electrolytes Injection, Type 2, USP) should be used with caution. Excess administration may result in metabolic alkalosis.

Laboratory Tests

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

Drug Interactions

Caution must be exercised in the administration of PLASMA-LYTE R Injection (Multiple Electrolytes Injection, Type 2, USP) to patients receiving corticosteroids or corticotropin.

Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with PLASMA-LYTE R Injection (Multiple Electrolytes Injection, Type 2, USP).

Carcinogenesis, mutagenesis, impairment of fertility

Studies with PLASMA-LYTE R Injection (Multiple Electrolytes Injection, Type 2, USP) have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy: Teratogenic Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with PLASMA-LYTE R Injection (Multiple Electrolytes Injection, Type 2, USP). It is also not known whether PLASMA-LYTE R Injection (Multiple Electrolytes Injection, Type 2, USP) can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. PLASMA-LYTE R Injection (Multiple Electrolytes Injection, Type 2, USP) should be given to a pregnant woman only if clearly needed.

Labor and Delivery

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100, 16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091, 16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055, 17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065, 17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029, 19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

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Studies have not been conducted to evaluate the effects of PLASMA-LYTE R Injection (Multiple Electrolytes Injection, Type 2, USP) on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when PLASMA-LYTE R Injection (Multiple Electrolytes Injection, Type 2, USP) is administered to a nursing woman.

Pediatric Use

Safety and effectiveness of PLASMA-LYTE R Injection (Multiple Electrolytes Injection, Type 2, USP) in pediatric patients have not been established by adequate and well controlled trials, however, the use of electrolyte solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

Geriatric Use

Clinical studies of PLASMA-LYTE R Injection (Multiple Electrolytes Injection, Type 2, USP) did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Adverse Reactions

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

Dosage and Administration

As directed by a physician. Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100,
16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091,
16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055,
17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065,
17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029,
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Do not administer unless solution is clear and seal is intact.

All injections in AVIVA plastic containers are intended for intravenous administration using sterile equipment.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

How Supplied

PLASMA-LYTE R Injection (Multiple Electrolytes Injection, Type 2, USP) in AVIVA plastic containers is available as shown below:

Code	Size (mL)	NDC
6E2504	1000	NDC 0338-6320-04

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure up to 40°C does not adversely affect the product.

Directions for Use of AVIVA Plastic Container

To Open

Tear overwrap down side at slit and remove solution container. Moisture and some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

Caution: Do not use plastic containers in series connections.

Caution: Use only with a non-vented set or a vented set with the vent closed.

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Additives may be incompatible.

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16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091,
16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055,
17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065,
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To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

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Deerfield, IL 60015 USA

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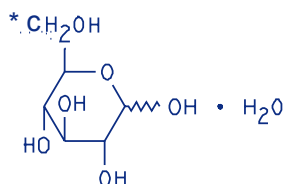
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PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) in AVIVA Plastic Container

Description

PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment and caloric supply in a single dose container for intravenous administration. Each 100 mL contains 5 g Dextrose Hydrous, USP*, 526 mg Sodium Chloride, USP (NaCl); 502 mg Sodium Gluconate (C₆H₁₁NaO₇); 368 mg Sodium Acetate Trihydrate, USP (C₂H₃NaO₂•3H₂O), 37 mg Potassium Chloride, USP (KCl); and 30 mg Magnesium Chloride, USP (MgCl₂•6H₂O). It contains no antimicrobial agents. The pH is 5.0 (4.0 to 6.5). The pH is adjusted with hydrochloric acid.



D-Glucopyranose monohydrate

PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) administered intravenously has value as a source of water, electrolytes, and calories. One liter has an ionic concentration of 140 mEq sodium, 5 mEq potassium, 3 mEq magnesium, 98 mEq chloride, 27 mEq acetate and 23 mEq gluconate. The osmolarity is 547 mOsmol/L (calc). Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L. Administration of substantially hypertonic solutions (≥ 600 mOsmol/L) may cause vein damage. The caloric content is 190 kcal/L.

The flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of paclitaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

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The suitability of the container materials has been established through biological evaluations, which have shown the container passes Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system.

The flexible container is a closed system, and air is prefilled in the container to facilitate drainage. The container does not require entry of external air during administration.

The container has two ports: one is the administration outlet port for attachment of an intravenous administration set and the other port has a medication site for addition of supplemental medication (See Directions for Use). The primary function of the overwrap is to protect the container from the physical environment.

Clinical Pharmacology

PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) has value as a source of water, electrolytes, and calories. It is capable of inducing diuresis depending on the clinical condition of the patient.

PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) produces a metabolic alkalinizing effect. Acetate and gluconate ions are metabolized ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

Indications and Usage

PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) is indicated as a source of water, electrolytes, and calories, or as an alkalinizing agent.

Contraindications

Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn products.

Warnings

PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency and in clinical states in which there exists edema with sodium retention.

PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be used with great care, if at all, in patients with hyperkalemia, severe renal failure and in conditions in which potassium retention is present.

PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be used with great care in patients with metabolic or respiratory alkalosis. The administration of acetate or gluconate ions should be done with great care in those conditions in which there is an increased level or an impaired utilization of these ions, such as severe hepatic insufficiency.

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The intravenous administration of PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injection. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection.

In patients with diminished renal function, administration of PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) may result in sodium or potassium retention.

Precautions

General

Do not connect flexible plastic containers of intravenous solutions in series, i.e., do not piggyback connections. Such use could result in air embolism due to residual air being drawn from one container before administration of the fluid from a secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be used with caution. Excess administration may result in metabolic alkalosis.

PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be used with caution in patients with overt or subclinical diabetes mellitus.

Laboratory Tests

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

Drug Interactions

Caution must be exercised in the administration of PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) to patients receiving corticosteroids or corticotropin.

Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP).

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Carcinogenesis, mutagenesis, impairment of fertility

Studies with PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy: Teratogenic Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP). It is also not known whether PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Studies have not been conducted to evaluate the effects of PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) is administered to a nursing mother.

Pediatric Use

Safety and effectiveness of PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) in pediatric patients have not been established by adequate and well controlled trials, however, the use of plasmalyte and dextrose solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

In very low birth weight infants, excessive or rapid administration of dextrose injection may result in increased serum osmolality and possible hemorrhage.

Geriatric Use

Clinical studies of PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or drug therapy.

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This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Adverse Reactions

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

Dosage and Administration

As directed by a physician. Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Do not administer unless solution is clear and seal is intact.

All injections in AVIVA plastic containers are intended for intravenous administration using sterile equipment.

As reported in the literature, the dosage and constant infusion rate of intravenous dextrose must be selected with caution in pediatric patients, particularly neonates and low weight infants, because of the increased risk of hyperglycemia/hypoglycemia.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

How Supplied

PLASMA-LYTE 148 and 5% Dextrose Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) in AVIVA plastic containers is available as shown below:

Size (mL)	Code	NDC
1000	6E2584	NDC 0338-6321-04
500	6E2583	NDC 0338-6321-03

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Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure up to 40°C does not adversely affect the product.

Directions for Use of AVIVA Plastic Container

To Open

Tear overwrap down side at slit and remove solution container. Moisture and some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

Caution: Do not use plastic containers in series connections.

Caution: Use only with a non-vented set or a vented set with the vent closed.

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Additives may be incompatible.

To add medication before solution administration

1. Prepare medication site.
 2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

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16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055,
17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065,
17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029,
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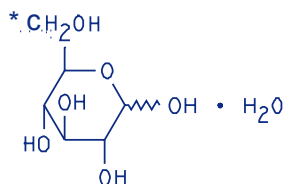
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5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) in AVIVA Plastic Container

Description

5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment and caloric supply in a single dose container for intravenous administration. Each 100 mL contains 5 g Dextrose Hydrous, USP*, 260 mg Sodium Lactate (C₃H₅NaO₃), 141 mg Potassium Chloride, USP (KCl), 31 mg Magnesium Chloride, USP (MgCl₂•6H₂O), 20 mg Monobasic Potassium Phosphate, NF (KH₂PO₄), and 12 mg Sodium Chloride, USP (NaCl). It contains no antimicrobial agents. pH 5.0 (4.0 to 6.5).



D-Glucopyranose monohydrate

5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) administered intravenously has value as a source of water, electrolytes, and calories. One liter has an ionic concentration of 25 mEq sodium, 20 mEq potassium, 3 mEq magnesium, 24 mEq chloride, 23 mEq lactate and 3 mEq phosphate as HPO₄⁻. The osmolarity is 348 mOsmol/L (calc). Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L. Administration of substantially hypertonic solutions (≥ 600 mOsmol/L) may cause vein damage. The caloric content is 180 kcal/L.

The flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of paclitaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

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The suitability of the container materials has been established through biological evaluations, which have shown the container passes Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system.

The flexible container is a closed system, and air is prefilled in the container to facilitate drainage. The container does not require entry of external air during administration.

The container has two ports: one is the administration outlet port for attachment of an intravenous administration set and the other port has a medication site for addition of supplemental medication (See Directions for Use). The primary function of the overwrap is to protect the container from the physical environment.

Clinical Pharmacology

5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) has value as a source of water, electrolytes and calories. It is capable of inducing diuresis depending on the clinical condition of the patient.

5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) produces a metabolic alkalinizing effect. Lactate ions are metabolized ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

Indications and Usage

5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) is indicated as a source of water, electrolytes, and calories or as an alkalinizing agent.

Contraindications

Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn products.

Warnings

5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be used with great care, if at all, in patients with hyperkalemia, severe renal failure, and in conditions in which potassium retention is present.

5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be used with great care in patients with metabolic or respiratory alkalosis. The administration of lactate ions should be done with great care in those conditions in which there is an increased level or an impaired utilization of these ions, such as severe hepatic insufficiency.

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5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should not be administered simultaneously with blood through the same administration set because of the possibility of pseudoagglutination or hemolysis.

The intravenous administration of 5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injection. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection.

In patients with diminished renal function, administration of 5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) may result in sodium or potassium retention.

5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) is not for use in the treatment of lactic acidosis.

Precautions

General

Do not connect flexible plastic containers of intravenous solutions in series, i.e., do not piggyback connections. Such use could result in air embolism due to residual air being drawn from one container before administration of the fluid from a secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

Do not administer simultaneously with blood.

5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be used with caution. Excess administration may result in metabolic alkalosis.

5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be used with caution in patients with overt or subclinical diabetes mellitus.

Laboratory Tests

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

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Drug Interactions

Caution must be exercised in the administration of 5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) to patients receiving corticosteroids or corticotropin.

Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with 5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP).

Carcinogenesis, mutagenesis, impairment of fertility

Studies with 5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy: Teratogenic Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with 5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP). It is also not known whether 5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. 5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Studies have not been conducted to evaluate the effects of 5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when 5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) is administered to a nursing mother.

Pediatric Use

Safety and effectiveness of 5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) in pediatric patients have not been established by adequate and well controlled trials, however, the use of dextrose and electrolytes solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

In very low birth weight infants, excessive or rapid administration of dextrose injection may result in increased serum osmolality and possible hemorrhage.

Geriatric Use

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Clinical studies of 5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in the responses between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Adverse Reactions

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

Dosage and Administration

As directed by a physician. Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Do not administer unless solution is clear and seal is intact.

All injections in AVIVA plastic containers are intended for intravenous administration using sterile equipment.

As reported in the literature, the dosage and constant infusion rate of intravenous dextrose must be selected with caution in pediatric patients, particularly neonates and low weight infants, because of the increased risk of hyperglycemia/hypoglycemia.

Additives may be incompatible. Complete information is not available.

Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

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How Supplied

5% Dextrose and Electrolyte No. 48 Injection (Multiple Electrolytes and Dextrose Injection, Type 1, USP) in AVIVA plastic containers is available as shown below:

Code	<u>Size (mL)</u>	NDC
6E2102	250	NDC 0338-6322-02
6E2103	500	NDC 0338-6322-03
6E2104	1000	NDC 0338-6322-04

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure up to 40°C does not adversely affect the product.

Directions for Use of AVIVA Plastic Container

To Open

Tear overwrap down side at slit and remove solution container. Moisture and some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

Caution: Do not use plastic containers in series connections.

Caution: Use only with a non-vented set or a vented set with the vent closed.

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Additives may be incompatible.

To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.

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16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055,
17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065,
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2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

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Potassium Chloride in 5% Dextrose Injection, USP in AVIVA Plastic Container

Description

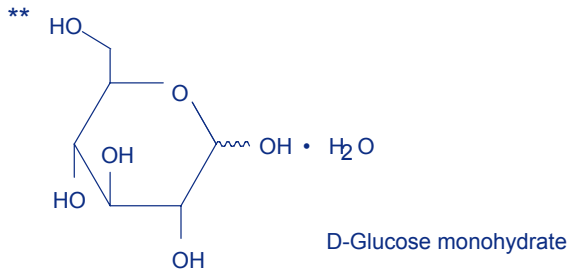
Potassium Chloride in 5% Dextrose Injection, USP is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment and caloric supply in a single dose container for intravenous administration. It contains no antimicrobial agents. Composition, osmolarity, pH, ionic concentration and caloric content are shown in Table 1.

Table 1

Potassium Chloride in 5% Dextrose Injection, USP mEq Potassium	Size (mL)	Composition (g/L)		*Osmolarity (mOsmol/L) (calc.)	pH	Ionic Concentration (mEq/L)		Caloric Content (kcal/L)
		**Dextrose Hydrous, USP	Potassium Chloride, USP (KCl)			Potassium	Chloride	
10 mEq	1000	50	0.75	272	4.5 (3.5 to 6.5)	10	10	170
20 mEq	1000	50	1.5	293	4.5 (3.5 to 6.5)	20	20	170
30 mEq	1000	50	2.24	312	4.5 (3.5 to 6.5)	30	30	170
40 mEq	1000	50	3	333	4.5 (3.5 to 6.5)	40	40	170
20 mEq	500							

*Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L.

Administration of substantially hypertonic solutions (≥ 600 mOsmol/L) may cause vein damage.



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The flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of paclitaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

The suitability of the container materials has been established through biological evaluations, which have shown the container passes Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system. The flexible container is a closed system, and air is pre-filled in the container to facilitate drainage. The container does not require entry of external air during administration.

The container has two ports: one is the administration outlet port for attachment of an intravenous administration set and the other port has a medication site for addition of supplemental medication (See Directions for Use). The primary function of the overwrap is to protect the container from the physical environment.

Clinical Pharmacology

Potassium Chloride in 5% Dextrose Injection, USP is a source of water, electrolytes and calories. It is capable of inducing diuresis depending on the clinical condition of the patient.

Indications and Usage

Potassium Chloride in 5% Dextrose Injection, USP is indicated as a source of water, electrolytes, and calories.

Contraindications

Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn products.

Warnings

Potassium Chloride in 5% Dextrose Injection, USP should be used with great care, if at all, in patients with hyperkalemia, severe renal failure, and in conditions in which potassium retention is present.

Injections containing carbohydrates with low electrolyte concentration should not be administered simultaneously with blood through the same administration set because of the possibility of pseudoagglutination or hemolysis. The bag label for these injections bears the statement: Do not administer simultaneously with blood.

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The intravenous administration of Potassium Chloride in 5% Dextrose Injection, USP can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injection. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection.

In patients with diminished renal function, administration of Potassium Chloride in 5% Dextrose Injection, USP may result in potassium retention.

In very low birth weight infants, excessive or rapid administration of dextrose injection may result in increased serum osmolality and possible intracerebral hemorrhage.

Potassium salts should never be administered by IV push.

Precautions

General

Do not connect flexible plastic containers of intravenous solutions in series, i.e., do not piggyback connections. Such use could result in air embolism due to residual air being drawn from one container before administration of the fluid from a secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

For patients receiving potassium supplement at greater than maintenance rates, frequent monitoring of serum potassium levels and serial EKGs are recommended.

Potassium Chloride in 5% Dextrose Injection, USP should be used with caution in patients with overt or subclinical diabetes mellitus.

Laboratory Tests

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

Drug Interactions

Studies have not been conducted to evaluate drug/drug or drug/food interactions with Potassium Chloride in 5% Dextrose Injection, USP.

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Carcinogenesis, mutagenesis, impairment of fertility

Studies with Potassium Chloride in 5% Dextrose Injection, USP have not been performed to evaluate carcinogenic potential, mutagenic potential or effects on fertility.

Pregnancy: Teratogenic Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with Potassium Chloride in 5% Dextrose Injection, USP. It is also not known whether Potassium Chloride in 5% Dextrose Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Potassium Chloride in 5% Dextrose Injection, USP should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Studies have not been conducted to evaluate the effects of Potassium Chloride in 5% Dextrose Injection, USP on labor and delivery. Caution should be exercised when administering this drug labor and delivery.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Potassium Chloride in 5% Dextrose Injection, USP is administered to a nursing mother.

Pediatric Use

Safety and effectiveness of Potassium Chloride in 5% Dextrose Injection in pediatric patients have not been established by adequate and well-controlled studies. However, the use of potassium chloride injection in pediatric patients to treat potassium deficiency states when oral replacement therapy is not feasible is referenced in the medical literature.

Dextrose is safe and effective for the stated indications in pediatric patients (see **Indication and Usage**). As reported in the literature, the dosage selection and constant infusion rate of intravenous dextrose must be selected with caution in pediatric patients, particularly neonates and low birth weight infants, because of the increased risk of hyperglycemia/hypoglycemia. Frequent monitoring of serum glucose concentrations is required when dextrose is prescribed to pediatric patients, particularly neonates and low birth weight infants.

Geriatric Use

Clinical studies of Potassium Chloride in 5% Dextrose Injection, USP did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in the responses between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or drug therapy.

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This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Adverse Reactions

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation, and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

Dosage and Administration

As directed by a physician. Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Use of a final filter is recommended during administration of all parenteral solutions, where possible. Do not administer unless solution is clear and seal is intact.

All injections in AVIVA plastic containers are intended for intravenous administration using sterile equipment.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

How Supplied

Potassium Chloride in 5% Dextrose Injection, USP in AVIVA plastic container is available as follows:

<u>Code</u>	<u>Size (mL)</u>	<u>NDC</u>	<u>Product Name</u>
6E1124	1000	0338-6323-04	10 mEq Potassium Chloride in 5% Dextrose Injection, USP
6E1134	1000	0338-6324-04	20 mEq Potassium Chloride in 5% Dextrose Injection, USP

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100, 16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091, 16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055, 17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065, 17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029, 19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

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6E1174	1000	0338-6325-04	30 mEq Potassium Chloride in 5% Dextrose Injection, USP
6E1264	1000	0338-6326-04	40 mEq Potassium Chloride in 5% Dextrose Injection, USP
6E1263	500	0338-6326-03	20 mEq Potassium Chloride in 5% Dextrose Injection, USP

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure up to 40°C does not adversely affect the product.

Directions for Use of AVIVA Plastic Container

To Open

Tear overwrap down side at slit and remove solution container. Moisture and some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

Caution: Do not use plastic containers in series connections.

Caution: Use only with a non-vented set or a vented set with the vent closed.

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Additives may be incompatible.

To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

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16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055,
17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065,
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1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

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Potassium Chloride in Sodium Chloride Injection, USP in AVIVA Plastic Container

Description

Potassium Chloride in Sodium Chloride Injection, USP is a sterile, nonpyrogenic, solution for fluid and electrolyte replenishment in a single dose container for intravenous administration. It contains no antimicrobial agents. Composition, osmolarity, pH and ionic concentration are shown in Table 1.

Table 1

	Size (mL)	Composition (g/L)		*Osmolarity (mOsmol/L) (Calc.)	pH	Ionic Concentration (mEq/L)		
		Sodium Chloride, USP (NaCl)	Potassium Chloride, USP (KCl)			Sodium	Potassium	Chloride
20 mEq/L Potassium Chloride in 0.9% Sodium Chloride Injection, USP	1000	9	1.5	348	5.5 (3.5 to 6.5)	154	20	174
40 mEq/L Potassium Chloride in 0.9% Sodium Chloride Injection, USP	1000	9	3	388	5.5 (3.5 to 6.5)	154	40	194

*Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L.

Administration of substantially hypertonic solutions (≥ 600 mOsmol/L) may cause vein damage.

The flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of paclitaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

The suitability of the container materials has been established through biological evaluations, which have shown the container passes Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system.

The flexible container is a closed system, and air is prefilled in the container to facilitate drainage. The container does not require entry of external air during administration.

The container has two ports: one is the administration outlet port for attachment of an intravenous administration set and the other port has a medication site for addition of supplemental medication

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(See Directions for Use). The primary function of the overwrap is to protect the container from the physical environment.

Clinical Pharmacology

Potassium Chloride in Sodium Chloride Injection, USP has value as a source of water and electrolytes. It is capable of inducing diuresis depending on the clinical condition of the patient.

Indications and Usage

Potassium Chloride in Sodium Chloride Injection, USP is indicated as a source of water and electrolytes.

Contraindications

None known

Warnings

Potassium Chloride in Sodium Chloride Injection, USP should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency and in clinical states in which there exists edema with sodium retention.

Potassium Chloride in Sodium Chloride Injection, USP should be used with great care, if at all, in patients with hyperkalemia, severe renal failure and in conditions in which potassium retention is present.

The intravenous administration of Potassium Chloride in Sodium Chloride Injection, USP can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injection. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection.

In patients with diminished renal function, administration of Potassium Chloride in Sodium Chloride Injection, USP may result in sodium or potassium retention.

Potassium salts should never be administered by IV push.

Precautions

General

Do not connect flexible plastic containers of intravenous solutions in series, i.e., do not piggyback connections. Such use could result in air embolism due to residual air being drawn from one container before administration of the fluid from a secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

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Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

For patients receiving potassium supplement at greater than maintenance rates, frequent monitoring of serum potassium levels and serial EKGs are recommended.

Laboratory Tests

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

Drug Interactions

Caution must be exercised in the administration of Potassium Chloride in Sodium Chloride Injection, USP to patients receiving corticosteroids or corticotropin.

Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with Potassium Chloride in Sodium Chloride Injection, USP.

Carcinogenesis, mutagenesis, impairment of fertility

Studies with Potassium Chloride in Sodium Chloride Injection, USP have not been performed to evaluate carcinogenic potential, mutagenic potential or effects on fertility.

Pregnancy: Teratogenic Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with Potassium Chloride in Sodium Chloride Injection, USP. It is also not known whether Potassium Chloride in Sodium Chloride Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Potassium Chloride in Sodium Chloride Injection, USP should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Studies have not been conducted to evaluate the effects of Potassium Chloride in Sodium Chloride Injection, USP on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Potassium Chloride in Sodium Chloride Injection, USP is administered to a nursing mother.

Pediatric Use

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Safety and effectiveness of Potassium Chloride in Sodium Chloride Injection, USP in pediatric patients have not been established by adequate and well-controlled studies. However, the use of potassium chloride injection in pediatric patients to treat potassium deficiency states when oral replacement therapy is not feasible is referenced in the medical literature.

Geriatric Use

Clinical studies of Potassium Chloride in Sodium Chloride Injection, USP did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in the responses between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Adverse Reactions

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

Dosage and Administration

As directed by a physician. Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Use of final filter is recommended during administration of all parenteral solutions, where possible. Do not administer unless solution is clear and seal is intact.

All injections in AVIVA plastic containers are intended for intravenous administration using sterile equipment.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

How Supplied

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Potassium Chloride in Sodium Chloride Injection, USP in AVIVA Plastic Container is available as follows:

Code	Size (mL)	NDC	Product Name
6E1764	1000	0338-6327-04	20 mEq/L Potassium Chloride in 0.9% Sodium Chloride Injection, USP
6E1984	1000	0338-6328-04	40 mEq/L Potassium Chloride in 0.9% Sodium Chloride Injection, USP

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25° C/77° F); brief exposure up to 40° C (104° F) does not adversely affect the product.

Directions for Use of AVIVA Plastic Container

To Open

Tear overwrap down side at slit and remove solution container. Moisture and some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

Caution: Do not use plastic containers in series connections.

Caution: Use only with a non-vented set or a vented set with the vent closed.

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Additives may be incompatible.

To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

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To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

Baxter Healthcare Corporation

Deerfield, IL 60015 USA

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* Bar Code Position Only

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Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP in AVIVA Plastic Container

Description

Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment and caloric supply in a single dose container for intravenous administration. It contains no antimicrobial agents. Composition, osmolarity, pH, ionic concentration and caloric content are shown in Table 1.

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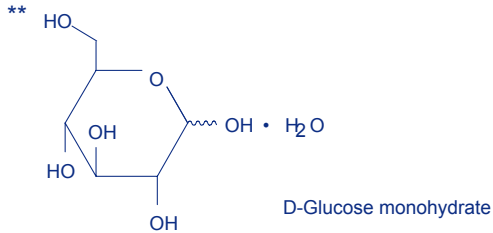
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Table 1

	Size (mL)	Composition (g/L)			*Osmolarity (mOsmol/L) (calc.)	pH	Ionic Concentration (mEq/L)			Caloric Content (kcal/L)
		**Dextrose Hydrous, USP	Sodium Chloride, USP (NaCl)	Potassium Chloride, USP (KCl)			Sodium	Potassium	Chloride	
Potassium Chloride in 5% Dextrose and 0.2% Sodium Chloride Injection, USP										
mEq Potassium										
10 mEq	1000	50	2	0.75	341	4.5 (3.5 to 6.5)	34	10	44	170
20 mEq 10 mEq	1000 500	50	2	1.5	361	4.5 (3.5 to 6.5)	34	20	54	170
30 mEq	1000	50	2	2.24	381	4.5 (3.5 to 6.5)	34	30	64	170
40 mEq	1000	50	2	3	401	4.5 (3.5 to 6.5)	34	40	74	170
Potassium Chloride in 5% Dextrose and 0.33% Sodium Chloride Injection, USP										
mEq Potassium										
20 mEq 10 mEq	1000 500	50	3.3	1.5	405	4.5 (3.5 to 6.5)	56	20	76	170
30 mEq	1000	50	3.3	2.24	425	4.5 (3.5 to 6.5)	56	30	86	170
40 mEq	1000	50	3.3	3	446	4.5 (3.5 to 6.5)	56	40	96	170
Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection, USP										
mEq Potassium										
10 mEq	1000	50	4.5	0.75	426	4.5 (3.5 to 6.5)	77	10	87	170
20 mEq 10 mEq	1000 500	50	4.5	1.5	447	4.5 (3.5 to 6.5)	77	20	97	170
30 mEq	1000	50	4.5	2.24	466	4.5 (3.5 to 6.5)	77	30	107	170
40 mEq	1000	50	4.5	3	487	4.5 (3.5 to 6.5)	77	40	117	170
Potassium Chloride in 5% Dextrose and 0.9% Sodium Chloride Injection, USP										
mEq Potassium										
20 mEq	1000	50	9	1.5	601	4.5 (3.5 to 6.5)	154	20	174	170
40 mEq	1000	50	9	3	641	4.5 (3.5 to 6.5)	154	40	194	170

*Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L.
 Administration of substantially hypertonic solutions (≥ 600 mOsmol/L) may cause vein damage.

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The flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of paclitaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

The suitability of the container materials has been established through biological evaluations, which have shown the container passes Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system.

The flexible container is a closed system, and air is prefilled in the container to facilitate drainage. The container does not require entry of external air during administration.

The container has two ports: one is the administration outlet port for attachment of an intravenous administration set and the other port has a medication site for addition of supplemental medication (See Directions for Use). The primary function of the overwrap is to protect the container from the physical environment.

Clinical Pharmacology

Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP has value as a source of water, electrolytes and calories. It is capable of inducing diuresis depending on the clinical condition of the patient.

Indications and Usage

Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP is indicated as a source of water, electrolytes and calories.

Contraindications

Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn products.

Warnings

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Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP should be used with great care, if at all, in patients with hyperkalemia, severe renal failure, and in conditions in which potassium retention is present.

Injections containing carbohydrates with low electrolyte concentration should not be administered simultaneously with blood through the same administration set because of the possibility of pseudoagglutination or hemolysis. The container label for these injections bears the statement: Do not administer simultaneously with blood.

The intravenous administration of Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injection. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection.

In patients with diminished renal function, administration of Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP may result in sodium or potassium retention.

In very low birth weight infants, excessive or rapid administration of dextrose injection may result in increased serum osmolality and possible intracerebral hemorrhage.

Potassium salts should never be administered by IV push.

Precautions

General

Do not connect flexible plastic containers of intravenous solutions in series, i.e., do not piggyback connections. Such use could result in air embolism due to residual air being drawn from one container before administration of the fluid from a secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

For patients receiving potassium supplement of greater than maintenance rates, frequent monitoring of serum potassium levels and serial EKGs are recommended.

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Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP should be used with caution in patients with overt or subclinical diabetes mellitus.

Laboratory Tests

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

Drug Interactions

Caution must be exercised in the administration of Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP to patients receiving corticosteroids or corticotropin.

Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP.

Carcinogenesis, mutagenesis, impairment of fertility

Studies with Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP have not been performed to evaluate carcinogenic potential, mutagenic potential or effects on fertility.

Pregnancy: Teratogenic Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP. It is also not known whether Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Studies have not been conducted to evaluate the effects of Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP is administered to a nursing mother.

Pediatric Use

Safety and effectiveness of Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP in pediatric patients have not been established by adequate and well-controlled studies. However, the use of potassium chloride injection in pediatric patients to treat potassium deficiency states when oral replacement therapy is not feasible is referenced in the medical literature.

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Dextrose is safe and effective for the stated indications in pediatric patients (see **Indications and Usage**). As reported in the literature, the dosage selection and constant infusion rate of intravenous dextrose must be selected with caution in pediatric patients, particularly neonates and low birth weight infants, because of the increased risk of hyperglycemia/hypoglycemia. Frequent monitoring of serum glucose concentrations is required when dextrose is prescribed to pediatric patients, particularly neonates and low birth weight infants.

Geriatric Use

Clinical studies of Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in the responses between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Adverse Reactions

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation, and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

Dosage and Administration

As directed by a physician. Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

Use of a final filter is recommended during administration of all parenteral solutions, where possible. Do not administer unless solution is clear and seal is intact.

All injections in AVIVA plastic containers are intended for intravenous administration using sterile equipment.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

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How Supplied

Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP in AVIVA plastic container is available as follows:

Code	Size (mL)	NDC	Product Name
6E1604	1000	0338-6334-04	10 mEq/L Potassium Chloride in 5% Dextrose and 0.2% Sodium Chloride Injection, USP
6E1614	1000	0338-6335-04	20 mEq/L Potassium Chloride in 5% Dextrose and 0.2% Sodium Chloride Injection, USP
6E1613	500	0338-6335-03	20 mEq/L Potassium Chloride in 5% Dextrose and 0.2% Sodium Chloride Injection, USP
6E1624	1000	0338-6336-04	30 mEq/L Potassium Chloride in 5% Dextrose and 0.2% Sodium Chloride Injection, USP
6E1634	1000	0338-6337-04	40 mEq/L Potassium Chloride in 5% Dextrose and 0.2% Sodium Chloride Injection, USP
6E1474	1000	0338-6348-04	20 mEq/L Potassium Chloride in 5% Dextrose and 0.33% Sodium Chloride Injection, USP
6E1473	500	0338-6348-03	20 mEq/L Potassium Chloride in 5% Dextrose and 0.33% Sodium Chloride Injection, USP
6E1484	1000	0338-6349-04	30 mEq/L Potassium Chloride in 5% Dextrose and 0.33% Sodium Chloride Injection, USP
6E1494	1000	0338-6350-04	40 mEq/L Potassium Chloride in 5% Dextrose and 0.33% Sodium Chloride Injection, USP
6E1644	1000	0338-6329-04	10 mEq/L Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection, USP
6E1654	1000	0338-6330-04	20 mEq/L Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection, USP
6E1653	500	0338-6330-03	20 mEq/L Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection, USP
6E1664	1000	0338-6331-04	30 mEq/L Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection, USP
6E1674	1000	0338-6332-04	40 mEq/L Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection, USP
6E2434	1000	0338-6342-04	20 mEq/L Potassium Chloride in 5% Dextrose and 0.9% Sodium Chloride Injection, USP
6E2454	1000	0338-6343-04	40 mEq/L Potassium Chloride in 5% Dextrose and 0.9% Sodium Chloride Injection, USP

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure to up to 40°C does not adversely affect the product.

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16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091,
16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055,
17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065,
17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029,
19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

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Directions for Use of AVIVA Plastic Container

To Open

Tear overwrap down side at slit and remove solution container. Moisture and some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

Caution: Do not use plastic containers in series connections.

Caution: Use only with a non-vented set or a vented set with the vent closed.

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Additives may be incompatible.

To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

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16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055,
17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065,
17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029,
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Sodium Chloride Injection, USP in AVIVA Plastic Container

Description

Sodium Chloride Injection, USP is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment in single dose containers for intravenous administration. It contains no antimicrobial agents. The pH is 5.5 (4.5 to 7.0). Composition, osmolarity, and ionic concentration are shown below.

0.45% Sodium Chloride Injection, USP contains 4.5 g/L Sodium Chloride, USP (NaCl) with an osmolarity of 154 mOsmol/L (calc). It contains 77 mEq/L sodium and 77 mEq/L chloride.

0.9% Sodium Chloride Injection, USP contains 9 g/L Sodium Chloride USP (NaCl) with an osmolarity of 308 mOsmol/L (calc). It contains 154 mEq/L sodium and 154 mEq/L chloride.

The flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of paclitaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

The suitability of the container materials has been established through biological evaluations, which have shown the container passes Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system.

The flexible container is a closed system, and air is prefilled in the container to facilitate drainage. The container does not require entry of external air during administration.

The container has two ports: one is the administration outlet port for attachment of an intravenous administration set and the other port has a medication site for addition of supplemental medication (See Directions for Use). The primary function of the overwrap is to protect the container from the physical environment.

Clinical Pharmacology

Sodium Chloride Injection, USP has value as a source of water and electrolytes. It is capable of inducing diuresis depending on the clinical condition of the patient.

Indications and Usage

Sodium Chloride Injection, USP is indicated as a source of water and electrolytes.

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0.9% Sodium Chloride Injection, USP is also indicated for use as a priming solution in hemodialysis procedures.

Contraindications

None known.

Warnings

Sodium Chloride Injection, USP should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

In patients with diminished renal function, administration of Sodium Chloride Injection, USP may result in sodium retention.

Precautions

General

Do not connect flexible plastic containers of intravenous solutions in series, i.e., do not piggyback connections. Such use could result in air embolism due to residual air being drawn from one container before administration of the fluid from a secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

Laboratory Tests

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

Drug Interactions

Caution must be exercised in the administration of Sodium Chloride Injection, USP to patients receiving corticosteroids or corticotropin.

Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with Sodium Chloride Injection, USP.

Carcinogenesis, mutagenesis, impairment of fertility

Studies with Sodium Chloride Injection, USP have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

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Pregnancy: Teratogenic Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with Sodium Chloride Injection, USP. It is also known whether Sodium Chloride Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium Chloride Injection, USP should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Studies have not been conducted to evaluate the effects of Sodium Chloride Injection, USP on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Sodium Chloride Injection, USP is administered to a nursing woman.

Pediatric Use

Safety and effectiveness of Sodium Chloride Injection, USP in pediatric patients have not been established by adequate and well controlled trials, however, the use of Sodium Chloride solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

Geriatric Use

Clinical studies of Sodium Chloride Injection, USP did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in the responses between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Adverse Reactions

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation, and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

Dosage and Administration

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As directed by a physician. Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Do not administer unless solution is clear and seal is intact.

All injections in AVIVA plastic containers are intended for intravenous administration using sterile equipment.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

How Supplied

The available sizes of each injection in AVIVA plastic containers are shown below:

Code	Size (mL)	NDC	Product Name
6E1313	500	0338-6333-03	0.45% Sodium Chloride Injection, USP
6E1314	1000	0338-6333-04	
6E1356	250	0338-6333-02	
6E1322	250	0338-6304-02	0.9% Sodium Chloride Injection, USP
6E1323	500	0338-6304-03	
6E1324	1000	0338-6304-04	

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C/77°F); brief exposure up to 40°C(104°F) does not adversely affect the product.

Directions for Use of AVIVA plastic container

To Open

Tear overwrap down side at slit and remove solution container. Moisture and some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

Caution: Do not use plastic containers in series connections.

Caution: Use only with a non-vented set or a vented set with the vent closed.

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100,
16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091,
16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055,
17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065,
17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029,
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1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Additives may be incompatible.

To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in-use position and continue administration.

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For Product Information

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16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091,
16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055,
17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065,
17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029,
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Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP in AVIVA Plastic Container

Description

Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment and caloric supply in a single dose container for intravenous administration. It contains no antimicrobial agents. Composition, osmolarity, pH, ionic concentration and caloric content are shown in Table 1.

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100,
 16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091,
 16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055,
 17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065,
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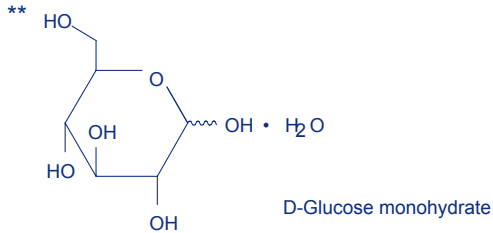
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Table 1

	Size (mL)	Composition (g/L)			*Osmolarity (mOsmol/L) (calc.)	pH	Ionic Concentration (mEq/L)			Caloric Content (kcal/L)
		**Dextrose Hydrous, USP	Sodium Chloride, USP (NaCl)	Potassium Chloride, USP (KCl)			Sodium	Potassium	Chloride	
Potassium Chloride in 5% Dextrose and 0.2% Sodium Chloride Injection, USP										
mEq Potassium										
10 mEq	1000	50	2	0.75	341	4.5 (3.5 to 6.5)	34	10	44	170
20 mEq 10 mEq	1000 500	50	2	1.5	361	4.5 (3.5 to 6.5)	34	20	54	170
30 mEq	1000	50	2	2.24	381	4.5 (3.5 to 6.5)	34	30	64	170
40 mEq	1000	50	2	3	401	4.5 (3.5 to 6.5)	34	40	74	170
Potassium Chloride in 5% Dextrose and 0.33% Sodium Chloride Injection, USP										
mEq Potassium										
20 mEq 10 mEq	1000 500	50	3.3	1.5	405	4.5 (3.5 to 6.5)	56	20	76	170
30 mEq	1000	50	3.3	2.24	425	4.5 (3.5 to 6.5)	56	30	86	170
40 mEq	1000	50	3.3	3	446	4.5 (3.5 to 6.5)	56	40	96	170
Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection, USP										
mEq Potassium										
10 mEq	1000	50	4.5	0.75	426	4.5 (3.5 to 6.5)	77	10	87	170
20 mEq 10 mEq	1000 500	50	4.5	1.5	447	4.5 (3.5 to 6.5)	77	20	97	170
30 mEq	1000	50	4.5	2.24	466	4.5 (3.5 to 6.5)	77	30	107	170
40 mEq	1000	50	4.5	3	487	4.5 (3.5 to 6.5)	77	40	117	170
Potassium Chloride in 5% Dextrose and 0.9% Sodium Chloride Injection, USP										
mEq Potassium										
20 mEq	1000	50	9	1.5	601	4.5 (3.5 to 6.5)	154	20	174	170
40 mEq	1000	50	9	3	641	4.5 (3.5 to 6.5)	154	40	194	170

*Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L.
 Administration of substantially hypertonic solutions (≥ 600 mOsmol/L) may cause vein damage.

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The flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of paclitaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

The suitability of the container materials has been established through biological evaluations, which have shown the container passes Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system.

The flexible container is a closed system, and air is prefilled in the container to facilitate drainage. The container does not require entry of external air during administration.

The container has two ports: one is the administration outlet port for attachment of an intravenous administration set and the other port has a medication site for addition of supplemental medication (See Directions for Use). The primary function of the overwrap is to protect the container from the physical environment.

Clinical Pharmacology

Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP has value as a source of water, electrolytes and calories. It is capable of inducing diuresis depending on the clinical condition of the patient.

Indications and Usage

Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP is indicated as a source of water, electrolytes and calories.

Contraindications

Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn products.

Warnings

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Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP should be used with great care, if at all, in patients with hyperkalemia, severe renal failure, and in conditions in which potassium retention is present.

Injections containing carbohydrates with low electrolyte concentration should not be administered simultaneously with blood through the same administration set because of the possibility of pseudoagglutination or hemolysis. The container label for these injections bears the statement: Do not administer simultaneously with blood.

The intravenous administration of Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injection. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection.

In patients with diminished renal function, administration of Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP may result in sodium or potassium retention.

In very low birth weight infants, excessive or rapid administration of dextrose injection may result in increased serum osmolality and possible intracerebral hemorrhage.

Potassium salts should never be administered by IV push.

Precautions

General

Do not connect flexible plastic containers of intravenous solutions in series, i.e., do not piggyback connections. Such use could result in air embolism due to residual air being drawn from one container before administration of the fluid from a secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

For patients receiving potassium supplement of greater than maintenance rates, frequent monitoring of serum potassium levels and serial EKGs are recommended.

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Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP should be used with caution in patients with overt or subclinical diabetes mellitus.

Laboratory Tests

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

Drug Interactions

Caution must be exercised in the administration of Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP to patients receiving corticosteroids or corticotropin.

Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP.

Carcinogenesis, mutagenesis, impairment of fertility

Studies with Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP have not been performed to evaluate carcinogenic potential, mutagenic potential or effects on fertility.

Pregnancy: Teratogenic Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP. It is also not known whether Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Studies have not been conducted to evaluate the effects of Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP is administered to a nursing mother.

Pediatric Use

Safety and effectiveness of Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP in pediatric patients have not been established by adequate and well-controlled studies. However, the use of potassium chloride injection in pediatric patients to treat potassium deficiency states when oral replacement therapy is not feasible is referenced in the medical literature.

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Dextrose is safe and effective for the stated indications in pediatric patients (see **Indications and Usage**). As reported in the literature, the dosage selection and constant infusion rate of intravenous dextrose must be selected with caution in pediatric patients, particularly neonates and low birth weight infants, because of the increased risk of hyperglycemia/hypoglycemia. Frequent monitoring of serum glucose concentrations is required when dextrose is prescribed to pediatric patients, particularly neonates and low birth weight infants.

Geriatric Use

Clinical studies of Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in the responses between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Adverse Reactions

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation, and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

Dosage and Administration

As directed by a physician. Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

Use of a final filter is recommended during administration of all parenteral solutions, where possible. Do not administer unless solution is clear and seal is intact.

All injections in AVIVA plastic containers are intended for intravenous administration using sterile equipment.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

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How Supplied

Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP in AVIVA plastic container is available as follows:

Code	Size (mL)	NDC	Product Name
6E1604	1000	0338-6334-04	10 mEq/L Potassium Chloride in 5% Dextrose and 0.2% Sodium Chloride Injection, USP
6E1614	1000	0338-6335-04	20 mEq/L Potassium Chloride in 5% Dextrose and 0.2% Sodium Chloride Injection, USP
6E1613	500	0338-6335-03	20 mEq/L Potassium Chloride in 5% Dextrose and 0.2% Sodium Chloride Injection, USP
6E1624	1000	0338-6336-04	30 mEq/L Potassium Chloride in 5% Dextrose and 0.2% Sodium Chloride Injection, USP
6E1634	1000	0338-6337-04	40 mEq/L Potassium Chloride in 5% Dextrose and 0.2% Sodium Chloride Injection, USP
6E1474	1000	0338-6348-04	20 mEq/L Potassium Chloride in 5% Dextrose and 0.33% Sodium Chloride Injection, USP
6E1473	500	0338-6348-03	20 mEq/L Potassium Chloride in 5% Dextrose and 0.33% Sodium Chloride Injection, USP
6E1484	1000	0338-6349-04	30 mEq/L Potassium Chloride in 5% Dextrose and 0.33% Sodium Chloride Injection, USP
6E1494	1000	0338-6350-04	40 mEq/L Potassium Chloride in 5% Dextrose and 0.33% Sodium Chloride Injection, USP
6E1644	1000	0338-6329-04	10 mEq/L Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection, USP
6E1654	1000	0338-6330-04	20 mEq/L Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection, USP
6E1653	500	0338-6330-03	20 mEq/L Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection, USP
6E1664	1000	0338-6331-04	30 mEq/L Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection, USP
6E1674	1000	0338-6332-04	40 mEq/L Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection, USP
6E2434	1000	0338-6342-04	20 mEq/L Potassium Chloride in 5% Dextrose and 0.9% Sodium Chloride Injection, USP
6E2454	1000	0338-6343-04	40 mEq/L Potassium Chloride in 5% Dextrose and 0.9% Sodium Chloride Injection, USP

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure to up to 40°C does not adversely affect the product.

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Directions for Use of AVIVA Plastic Container

To Open

Tear overwrap down side at slit and remove solution container. Moisture and some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

Caution: Do not use plastic containers in series connections.

Caution: Use only with a non-vented set or a vented set with the vent closed.

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Additives may be incompatible.

To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

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* Bar Code Position Only
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Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP in AVIVA Plastic Container

Description

Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment and caloric supply in a single dose container for intravenous administration. It contains no antimicrobial agents. Composition, osmolarity, pH, ionic concentration and caloric content are shown in Table 1.

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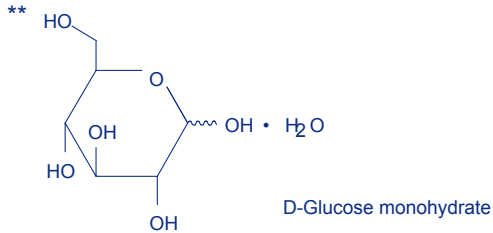
Table 1

	Size (mL)	Composition (g/L)			*Osmolarity (mOsmol/L) (calc.)	pH	Ionic Concentration (mEq/L)			Caloric Content (kcal/L)
		**Dextrose Hydrous, USP	Sodium Chloride, USP (NaCl)	Potassium Chloride, USP (KCl)			Sodium	Potassium	Chloride	
Potassium Chloride in 5% Dextrose and 0.2% Sodium Chloride Injection, USP										
mEq Potassium										
10 mEq	1000	50	2	0.75	341	4.5 (3.5 to 6.5)	34	10	44	170
20 mEq 10 mEq	1000 500	50	2	1.5	361	4.5 (3.5 to 6.5)	34	20	54	170
30 mEq	1000	50	2	2.24	381	4.5 (3.5 to 6.5)	34	30	64	170
40 mEq	1000	50	2	3	401	4.5 (3.5 to 6.5)	34	40	74	170
Potassium Chloride in 5% Dextrose and 0.33% Sodium Chloride Injection, USP										
mEq Potassium										
20 mEq 10 mEq	1000 500	50	3.3	1.5	405	4.5 (3.5 to 6.5)	56	20	76	170
30 mEq	1000	50	3.3	2.24	425	4.5 (3.5 to 6.5)	56	30	86	170
40 mEq	1000	50	3.3	3	446	4.5 (3.5 to 6.5)	56	40	96	170
Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection, USP										
mEq Potassium										
10 mEq	1000	50	4.5	0.75	426	4.5 (3.5 to 6.5)	77	10	87	170
20 mEq 10 mEq	1000 500	50	4.5	1.5	447	4.5 (3.5 to 6.5)	77	20	97	170
30 mEq	1000	50	4.5	2.24	466	4.5 (3.5 to 6.5)	77	30	107	170
40 mEq	1000	50	4.5	3	487	4.5 (3.5 to 6.5)	77	40	117	170
Potassium Chloride in 5% Dextrose and 0.9% Sodium Chloride Injection, USP										
mEq Potassium										
20 mEq	1000	50	9	1.5	601	4.5 (3.5 to 6.5)	154	20	174	170
40 mEq	1000	50	9	3	641	4.5 (3.5 to 6.5)	154	40	194	170

*Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L.
 Administration of substantially hypertonic solutions (≥ 600 mOsmol/L) may cause vein damage.

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The flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of paclitaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

The suitability of the container materials has been established through biological evaluations, which have shown the container passes Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system.

The flexible container is a closed system, and air is prefilled in the container to facilitate drainage. The container does not require entry of external air during administration.

The container has two ports: one is the administration outlet port for attachment of an intravenous administration set and the other port has a medication site for addition of supplemental medication (See Directions for Use). The primary function of the overwrap is to protect the container from the physical environment.

Clinical Pharmacology

Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP has value as a source of water, electrolytes and calories. It is capable of inducing diuresis depending on the clinical condition of the patient.

Indications and Usage

Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP is indicated as a source of water, electrolytes and calories.

Contraindications

Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn products.

Warnings

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Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP should be used with great care, if at all, in patients with hyperkalemia, severe renal failure, and in conditions in which potassium retention is present.

Injections containing carbohydrates with low electrolyte concentration should not be administered simultaneously with blood through the same administration set because of the possibility of pseudoagglutination or hemolysis. The container label for these injections bears the statement: Do not administer simultaneously with blood.

The intravenous administration of Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injection. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection.

In patients with diminished renal function, administration of Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP may result in sodium or potassium retention.

In very low birth weight infants, excessive or rapid administration of dextrose injection may result in increased serum osmolality and possible intracerebral hemorrhage.

Potassium salts should never be administered by IV push.

Precautions

General

Do not connect flexible plastic containers of intravenous solutions in series, i.e., do not piggyback connections. Such use could result in air embolism due to residual air being drawn from one container before administration of the fluid from a secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

For patients receiving potassium supplement of greater than maintenance rates, frequent monitoring of serum potassium levels and serial EKGs are recommended.

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Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP should be used with caution in patients with overt or subclinical diabetes mellitus.

Laboratory Tests

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

Drug Interactions

Caution must be exercised in the administration of Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP to patients receiving corticosteroids or corticotropin.

Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP.

Carcinogenesis, mutagenesis, impairment of fertility

Studies with Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP have not been performed to evaluate carcinogenic potential, mutagenic potential or effects on fertility.

Pregnancy: Teratogenic Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP. It is also not known whether Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Studies have not been conducted to evaluate the effects of Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP is administered to a nursing mother.

Pediatric Use

Safety and effectiveness of Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP in pediatric patients have not been established by adequate and well-controlled studies. However, the use of potassium chloride injection in pediatric patients to treat potassium deficiency states when oral replacement therapy is not feasible is referenced in the medical literature.

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Dextrose is safe and effective for the stated indications in pediatric patients (see **Indications and Usage**). As reported in the literature, the dosage selection and constant infusion rate of intravenous dextrose must be selected with caution in pediatric patients, particularly neonates and low birth weight infants, because of the increased risk of hyperglycemia/hypoglycemia. Frequent monitoring of serum glucose concentrations is required when dextrose is prescribed to pediatric patients, particularly neonates and low birth weight infants.

Geriatric Use

Clinical studies of Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in the responses between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Adverse Reactions

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation, and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

Dosage and Administration

As directed by a physician. Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

Use of a final filter is recommended during administration of all parenteral solutions, where possible. Do not administer unless solution is clear and seal is intact.

All injections in AVIVA plastic containers are intended for intravenous administration using sterile equipment.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

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How Supplied

Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP in AVIVA plastic container is available as follows:

Code	Size (mL)	NDC	Product Name
6E1604	1000	0338-6334-04	10 mEq/L Potassium Chloride in 5% Dextrose and 0.2% Sodium Chloride Injection, USP
6E1614	1000	0338-6335-04	20 mEq/L Potassium Chloride in 5% Dextrose and 0.2% Sodium Chloride Injection, USP
6E1613	500	0338-6335-03	20 mEq/L Potassium Chloride in 5% Dextrose and 0.2% Sodium Chloride Injection, USP
6E1624	1000	0338-6336-04	30 mEq/L Potassium Chloride in 5% Dextrose and 0.2% Sodium Chloride Injection, USP
6E1634	1000	0338-6337-04	40 mEq/L Potassium Chloride in 5% Dextrose and 0.2% Sodium Chloride Injection, USP
6E1474	1000	0338-6348-04	20 mEq/L Potassium Chloride in 5% Dextrose and 0.33% Sodium Chloride Injection, USP
6E1473	500	0338-6348-03	20 mEq/L Potassium Chloride in 5% Dextrose and 0.33% Sodium Chloride Injection, USP
6E1484	1000	0338-6349-04	30 mEq/L Potassium Chloride in 5% Dextrose and 0.33% Sodium Chloride Injection, USP
6E1494	1000	0338-6350-04	40 mEq/L Potassium Chloride in 5% Dextrose and 0.33% Sodium Chloride Injection, USP
6E1644	1000	0338-6329-04	10 mEq/L Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection, USP
6E1654	1000	0338-6330-04	20 mEq/L Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection, USP
6E1653	500	0338-6330-03	20 mEq/L Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection, USP
6E1664	1000	0338-6331-04	30 mEq/L Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection, USP
6E1674	1000	0338-6332-04	40 mEq/L Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection, USP
6E2434	1000	0338-6342-04	20 mEq/L Potassium Chloride in 5% Dextrose and 0.9% Sodium Chloride Injection, USP
6E2454	1000	0338-6343-04	40 mEq/L Potassium Chloride in 5% Dextrose and 0.9% Sodium Chloride Injection, USP

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure to up to 40°C does not adversely affect the product.

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Directions for Use of AVIVA Plastic Container

To Open

Tear overwrap down side at slit and remove solution container. Moisture and some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

Caution: Do not use plastic containers in series connections.

Caution: Use only with a non-vented set or a vented set with the vent closed.

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Additives may be incompatible.

To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

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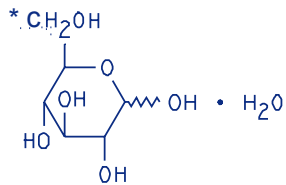
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5% Dextrose and Electrolyte No. 75 Injection (Multiple Electrolytes and Dextrose Injection, Type 3, USP) in AVIVA Plastic Container

Description

5% Dextrose and Electrolyte No. 75 Injection (Multiple Electrolytes and Dextrose Injection, Type 3, USP) is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment and caloric supply in a single dose container for intravenous administration. Each 100 mL contains 5 g Dextrose Hydrous, USP*, 220 mg Sodium Lactate (C₃H₅NaO₃), 205 mg Potassium Chloride, USP (KCl), 120 mg Sodium Chloride, USP (NaCl), and 100 mg Monobasic Potassium Phosphate, NF (KH₂PO₄). It contains no antimicrobial agents. pH 5.0 (4.0 to 6.5).



D-Glucopyranose monohydrate

5% Dextrose and Electrolyte No. 75 Injection (Multiple Electrolytes and Dextrose Injection, Type 3, USP) administered intravenously has value as a source of water, electrolytes, and calories. One liter has an ionic concentration of 40 mEq sodium, 35 mEq potassium, 48 mEq chloride, 20 mEq lactate, and 15 mEq phosphate as HPO₄⁻. The osmolarity is 402 mOsmol/L (calc). Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L. Administration of substantially hypertonic solutions (≥ 600 mOsmol/L) may cause vein damage. The caloric content is 180 kcal/L.

The flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of paclitaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

The suitability of the container materials has been established through biological evaluations, which have shown the container passes Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system.

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The flexible container is a closed system, and air is prefilled in the container to facilitate drainage. The container does not require entry of external air during administration.

The container has two ports: one is the administration outlet port for attachment of an intravenous administration set and the other port has a medication site for addition of supplemental medication (See Directions for Use). The primary function of the overwrap is to protect the container from the physical environment.

Clinical Pharmacology

5% Dextrose and Electrolyte No. 75 Injection (Multiple Electrolytes and Dextrose Injection, Type 3, USP) has value as a source of water, electrolytes and calories. It is capable of inducing diuresis depending on the clinical condition of the patient.

5% Dextrose and Electrolyte No. 75 Injection (Multiple Electrolytes and Dextrose Injection, Type 3, USP) produces a metabolic alkalinizing effect. Lactate ions are metabolized in the liver to glycogen, and ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

Indications and Usage

5% Dextrose and Electrolyte No. 75 Injection (Multiple Electrolytes and Dextrose Injection, Type 3, USP) is indicated as a source of water, electrolytes and calories or as an alkalinizing agent.

Contraindications

Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn products.

Warnings

5% Dextrose and Electrolyte No. 75 Injection (Multiple Electrolytes and Dextrose Injection, Type 3, USP) should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

5% Dextrose and Electrolyte No. 75 Injection (Multiple Electrolytes and Dextrose Injection, Type 3, USP) should be used with great care, if at all, in patients with hyperkalemia, severe renal failure, and in conditions in which potassium retention is present.

5% Dextrose and Electrolyte No. 75 Injection (Multiple Electrolytes and Dextrose Injection, Type 3, USP) should be used with great care in patients with metabolic or respiratory alkalosis. The administration of lactate ions should be done with great care in those conditions in which there is an increased level or an impaired utilization of these ions, such as severe hepatic insufficiency.

The intravenous administration of 5% Dextrose and Electrolyte No. 75 Injection (Multiple Electrolytes and Dextrose Injection, Type 3, USP) can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of

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dilutional states is inversely proportional to the electrolyte concentrations of the injection. The risk of solute overloading causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection.

In patients with diminished renal function, administration of 5% Dextrose and Electrolyte No. 75 Injection (Multiple Electrolytes and Dextrose Injection, Type 3, USP) may result in sodium or potassium retention.

5% Dextrose and Electrolyte No. 75 Injection (Multiple Electrolytes and Dextrose Injection, Type 3, USP) is not for use in the treatment of lactic acidosis.

Precautions

General

Do not connect flexible plastic containers of intravenous solutions in series, i.e., do not piggyback connections. Such use could result in air embolism due to residual air being drawn from one container before administration of the fluid from a secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

5% Dextrose and Electrolyte No. 75 Injection (Multiple Electrolytes and Dextrose Injection, Type 3, USP) should be used with caution. Excess administration may result in metabolic alkalosis.

5% Dextrose and Electrolyte No. 75 Injection (Multiple Electrolytes and Dextrose Injection, Type 3, USP) should be used with caution in patients with overt or subclinical diabetes mellitus.

Laboratory Tests

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

Drug Interactions

Caution must be exercised in the administration of 5% Dextrose and Electrolyte No. 75 Injection (Multiple Electrolytes and Dextrose Injection, Type 3, USP) to patients receiving corticosteroids or corticotropin.

Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with 5% Dextrose and Electrolyte No. 75 Injection (Multiple Electrolytes and Dextrose Injection, Type 3, USP).

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Carcinogenesis, mutagenesis, impairment of fertility

Studies with 5% Dextrose and Electrolyte No. 75 Injection (Multiple Electrolytes and Dextrose Injection, Type 3, USP) have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy: Teratogenic Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with 5% Dextrose and Electrolyte No. 75 Injection (Multiple Electrolytes and Dextrose Injection, Type 3, USP). It is also not known whether 5% Dextrose and Electrolyte No. 75 Injection (Multiple Electrolytes and Dextrose Injection, Type 3, USP) can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. 5% Dextrose and Electrolyte No. 75 Injection (Multiple Electrolytes and Dextrose Injection, Type 3, USP) should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Studies have not been conducted to evaluate the effects of 5% Dextrose and Electrolyte No. 75 Injection (Multiple Electrolytes and Dextrose Injection, Type 3, USP) on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

Nursing Mothers

IT IS NOT KNOWN WHETHER THIS DRUG IS EXCRETED IN HUMAN MILK. BECAUSE MANY DRUGS ARE EXCRETED IN HUMAN MILK, CAUTION SHOULD BE EXERCISED WHEN 5% DEXTROSE AND ELECTROLYTE NO. 75 INJECTION (MULTIPLE ELECTROLYTES AND DEXTROSE INJECTION, TYPE 3, USP) IS ADMINISTERED TO A NURSING MOTHER.

Pediatric Use

Safety and effectiveness of 5% Dextrose and Electrolyte No. 75 Injection (Multiple Electrolytes and Dextrose Injection, Type 3, USP) in pediatric patients have not been established by adequate and well controlled trials, however, the use of dextrose and electrolyte solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

In very low birth weight infants, excessive or rapid administration of dextrose injection may result in increased serum osmolality and possible hemorrhage.

Geriatric Use

Clinical studies of 5% Dextrose and Electrolyte No. 75 Injection (Multiple Electrolytes and Dextrose Injection, Type 3, USP) did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in the responses between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or drug therapy.

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This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Adverse Reactions

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

Dosage and Administration

As directed by a physician. Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Do not administer unless solution is clear and seal is intact.

All injections in AVIVA plastic containers are intended for intravenous administration using sterile equipment.

As reported in the literature, the dosage and constant infusion rate of intravenous dextrose must be selected with caution in pediatric patients, particularly neonates and low weight infants, because of the increased risk of hyperglycemia/hypoglycemia.

Additives may be incompatible. Complete information is not available.

Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

How Supplied

5% Dextrose and Electrolyte No. 75 Injection (Multiple Electrolytes and Dextrose Injection, Type 3, USP) in AVIVA plastic containers is available as shown below:

Code	<u>Size (mL)</u>	NDC
6E2112	250	NDC 0338-6338-02
6E2113	500	NDC 0338-6338-03

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6E2114

1000

NDC 0338-6338-04

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure up to 40°C does not adversely affect the product.

Directions for Use of AVIVA Plastic Container

To Open

Tear overwrap down side at slit and remove solution container. Moisture and some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

Caution: Do not use plastic containers in series connections.

Caution: Use only with a non-vented set or a vented set with the vent closed.

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Additives may be incompatible.

To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

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3% and 5% Sodium Chloride Injection, USP in AVIVA Plastic Container

Description

3% and 5% Sodium Chloride Injection, USP is a sterile, nonpyrogenic, hypertonic solution for fluid and electrolyte replenishment in single dose containers for intravenous administration. The pH may have been adjusted with hydrochloric acid. It contains no antimicrobial agents. Composition, ionic concentration, osmolarity, and pH are shown in Table 1.

Table 1

	size (mL)	Composition (g/L)	Ionic Concentration (mEq/L)		*Osmolarity (mOsmol/L) (calc)	pH
		Sodium Chloride USP (NaCl)	Sodium	Chloride		
3% Sodium Chloride Injection, USP	500	30	513	513	1027	5.5 (4.5 to 7.0)
5% Sodium Chloride Injection, USP	500	50	856	856	1711	5.5 (4.5 to 7.0)

*Normal physiological osmolarity range is approximately 280 to 310 mOsmol/L. Administration of substantially hypertonic solutions (≥ 600 mOsmol/L) may cause vein damage.

The flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of paclitaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

The suitability of the container materials has been established through biological evaluations, which have shown the container passes Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system.

The flexible container is a closed system, and air is prefilled in the container to facilitate drainage. The container does not require entry of external air during administration.

The container has two ports: one is the administration outlet port for attachment of an intravenous administration set and the other port has a medication site for addition of supplemental medication (See Directions for Use). The primary function of the overwrap is to protect the container from the physical environment.

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Clinical Pharmacology

3% and 5% Sodium Chloride Injection, USP has value as a source of water and electrolytes. It is capable of inducing diuresis depending on the clinical condition of the patient.

Indications and Usage

3% and 5% Sodium Chloride Injection, USP is indicated as a source of water and electrolytes.

Contraindications

None known

Warnings

3% and 5% Sodium Chloride Injection, USP is strongly hypertonic and may cause vein damage.

3% and 5% Sodium Chloride Injection, USP should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

In patients with diminished renal function, administration of 3% and 5% Sodium Chloride Injection, USP may result in sodium retention.

Precautions

General

Do not connect flexible plastic containers of intravenous solutions in series, i.e., do not piggyback connections. Such use could result in air embolism due to residual air being drawn from one container before administration of the fluid from a secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

Laboratory Tests

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

Drug Interactions

Caution must be exercised in the administration of 3% and 5% Sodium Chloride Injection, USP to patients receiving corticosteroids or corticotropin.

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Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with 3% and 5% Sodium Chloride Injection, USP.

Carcinogenesis, mutagenesis, impairment of fertility

Studies with 3% and 5% Sodium Chloride Injection, USP have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy: Teratogenic Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with 3% and 5% Sodium Chloride Injection, USP. It is also not known whether 3% and 5% Sodium Chloride Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. 3% and 5% Sodium Chloride Injection, USP should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Studies have not been conducted to evaluate the effects of 3% and 5% Sodium Chloride Injection, USP on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when 3% and 5% Sodium Chloride Injection, USP is administered to a nursing woman.

Pediatric Use

Safety and effectiveness of 3% and 5% Sodium Chloride Injection, USP in pediatric patients have not been established by adequate and well controlled trials, however, the use of sodium chloride solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

Geriatric Use

Clinical studies of 3% and 5% Sodium Chloride Injection, USP did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in the responses between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

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Adverse Reactions

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

Dosage and Administration

As directed by a physician. Dosage is dependent upon the age, weight, and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Use of a final filter is recommended during administration of all parenteral solutions, where possible. Do not administer unless solution is clear and seal is intact.

All injections in AVIVA plastic containers are intended for intravenous administration using sterile equipment.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

How Supplied

3% and 5% Sodium Chloride Injection, USP in AVIVA Plastic Container is available as follows:

Code	Size (mL)	NDC	Product Name
6E1353	500	0338-6339-03	3% Sodium Chloride Injection, USP
6E1373	500	0338-6340-03	5% Sodium Chloride Injection, USP

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure to up to 40°C does not adversely affect the product.

Directions for Use of AVIVA Plastic Container To Open

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17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065,
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Tear overwrap down side at slit and remove solution container. Moisture and some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

Caution: Do not use plastic containers in series connections.

Caution: Use only with a non-vented set or a vented set with the vent closed.

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Additives may be incompatible.

To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

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PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP)

in AVIVA Plastic Container

Description

PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP) is a sterile, nonpyrogenic, hypotonic solution in a single dose container for intravenous administration. Each 100 mL contains 234 mg of Sodium Chloride, USP (NaCl); 128 mg of Potassium Acetate, USP ($C_2H_3KO_2$); and 32 mg of Magnesium Acetate Tetrahydrate ($Mg(C_2H_3O_2)_2 \cdot 4H_2O$). It contains no antimicrobial agents. The pH is adjusted with hydrochloric acid. The pH is 5.5 (4.0 to 8.0).

PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP) administered intravenously has value as a source of water and electrolytes. One liter has an ionic concentration of 40 mEq sodium, 13 mEq potassium, 3 mEq magnesium, 40 mEq chloride, and 16 mEq acetate. The osmolarity is 111 mOsmol/L (calc). Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L. Administration of substantially hypertonic solutions may cause vein damage.

The flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of paclitaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

The suitability of the container materials has been established through biological evaluations, which have shown the container passes Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system.

The flexible container is a closed system, and air is prefilled in the container to facilitate drainage. The container does not require entry of external air during administration.

The container has two ports: one is the administration outlet port for attachment of an intravenous administration set and the other port has a medication site for addition of supplemental medication (See Directions for Use). The primary function of the overwrap is to protect the container from the physical environment.

Clinical Pharmacology

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PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP) has value as a source of water and electrolytes. It is capable of inducing diuresis depending on the clinical condition of the patient.

PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP) produces a metabolic alkalinizing effect. Acetate ions are metabolized ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

Indications and Usage

PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP) is indicated as a source of water and electrolytes or as an alkalinizing agent.

Contraindications

None known

Warnings

PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP) should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency and in clinical states in which there exists edema with sodium retention.

PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP) should be used with great care, if at all, in patients with hyperkalemia, severe renal failure and in conditions in which potassium retention is present.

PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP) should be used with great care in patients with metabolic or respiratory alkalosis. The administration of acetate ions should be done with great care in those conditions in which there is an increased level or an impaired utilization of these ions, such as severe hepatic insufficiency.

PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP) should not be administered simultaneously with blood through the same administration set because of the possibility of hemolysis.

The intravenous administration of PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP) can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injection. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection.

In patients with diminished renal function, administration of PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP) may result in sodium or potassium retention.

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Precautions

General

Do not connect flexible plastic containers of intravenous solutions in series, i.e., do not piggyback connections. Such use could result in air embolism due to residual air being drawn from one container before administration of the fluid from a secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP) should be used with caution. Excess administration may result in metabolic alkalosis.

Laboratory Tests

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

Drug Interactions

Caution must be exercised in the administration of PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP) to patients receiving corticosteroids or corticotropin.

Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP).

Carcinogenesis, mutagenesis, impairment of fertility

Studies with PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP) have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy: Teratogenic Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP). It is also not known whether PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP) can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP) should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Studies have not been conducted to evaluate the effects of PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP) on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

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Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP) is administered to a nursing woman.

Pediatric Use

Safety and effectiveness of PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP) in pediatric patients have not been established by adequate and well controlled trials, however, the use of electrolyte solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

Geriatric Use

Clinical studies of PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP) did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Adverse Reactions

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

Dosage and Administration

As directed by a physician. Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

Do not administer unless solution is clear and seal is intact.

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All injections in AVIVA plastic containers are intended for intravenous administration using sterile equipment.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

How Supplied

PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP) in AVIVA plastic containers is available as shown below:

Code	Size (mL)	NDC
6E2524	1000	NDC 0338-6341-04

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure up to 40°C does not adversely affect the product.

Directions for Use of AVIVA Plastic Container

To Open

Tear overwrap down side at slit and remove solution container. Moisture and some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

Caution: Do not use plastic containers in series connections.

Caution: Use only with a non-vented set or a vented set with the vent closed.

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Additives may be incompatible.

To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

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To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

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Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP in AVIVA Plastic Container

Description

Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment and caloric supply in a single dose container for intravenous administration. It contains no antimicrobial agents. Composition, osmolarity, pH, ionic concentration and caloric content are shown below:

Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP	Size (mL)	Composition (g/L)					*Osmolarity (mOsmol/L) (calc.)
		**Dextrose Hydrous, USP	Sodium Chloride, USP (NaCl)	Sodium Lactate, (C ₃ H ₅ NaO ₃)	Potassium Chloride, USP (KCl)	Calcium Chloride, USP (CaCl ₂ •2H ₂ O)	
mEq Potassium added							
20 mEq	1000	50	6	3.1	1.79	0.2	565
40 mEq	1000	50	6	3.1	3.28	0.2	605

*Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L.

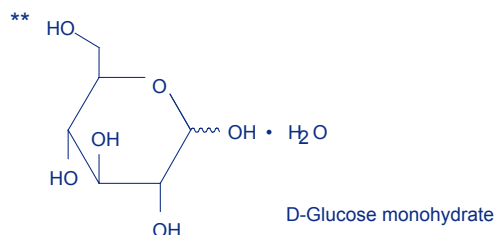
Administration of substantially hypertonic solutions (≥ 600 mOsmol/L) may cause vein damage.

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Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP	pH	Ionic Concentration (mEq/L)					Caloric Content (kcal/L)
		Sodium	Potassium	Calcium	Chloride	Lactate	
mEq Potassium added							
20 mEq	5.0 (3.5 to 6.5)	130	24	3	129	28	170
40 mEq	5.0 (3.5 to 6.5)	130	44	3	149	28	170

** The chemical structure for Dextrose Hydrus, USP is shown below:



The flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of paclitaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

The suitability of the container materials has been established through biological evaluations, which have shown the container passes Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system.

The flexible container is a closed system, and air is prefilled in the container to facilitate drainage. The container does not require entry of external air during administration.

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The container has two ports: one is the administration outlet port for attachment of an intravenous administration set and the other port has a medication site for addition of supplemental medication (See Directions for Use). The primary function of the overwrap is to protect the container from the physical environment.

Clinical Pharmacology

Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP have value as a source of water, electrolytes, and calories. It is capable of inducing diuresis depending on the clinical condition of the patient.

Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP produce a metabolic alkalinizing effect. Lactate ions are metabolized ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

Indications and Usage

Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP are indicated as a source of water, electrolytes, and calories or as alkalinizing agents.

Contraindications

Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn product.

Warnings

Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP should be used with great care, if at all, in patients with hyperkalemia, severe renal failure, and in conditions in which potassium retention is present.

Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP should be used with great care, if at all, in patients with metabolic or respiratory alkalosis. The administration of lactate ions should be done with great care in those conditions in which there is an increased level or an impaired utilization of these ions, such as severe hepatic insufficiency.

Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP should not be administered with blood through the same administration set because of the likelihood of coagulation.

The intravenous administration of Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injection. The risk of solute overload causing

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congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection.

In patients with diminished renal function, administration of Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP may result in sodium or potassium retention.

Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP are not for use in the treatment of lactic acidosis.

In very low birth weight infants, excessive or rapid administration of dextrose injection may result in increased serum osmolality and possible intracerebral hemorrhage.

Potassium salts should never be administered by IV push.

Precautions

General

Do not connect flexible plastic containers of intravenous solutions in series, i.e., do not piggyback connections. Such use could result in air embolism due to residual air being drawn from one container before administration of the fluid from a secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP should be used with caution. Excess administration may result in metabolic alkalosis.

Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP should be used with caution in patients with overt or subclinical diabetes mellitus.

Laboratory Tests

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

Drug Interactions

Caution must be exercised in the administration of Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP to patients receiving corticosteroids or corticotropin.

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Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP.

Carcinogenesis, mutagenesis, impairment of fertility

Studies with Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy: Teratogenic Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP. It is also not known whether Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Studies have not been conducted to evaluate the effects of Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP is administered to a nursing mother.

Pediatric Use

Safety and effectiveness of Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP in pediatric patients have not been established by adequate and well controlled studies. However, the use of potassium chloride injection in pediatric patients to treat potassium deficiency states when oral replacement therapy is not feasible is referenced in the medical literature.

Dextrose is safe and effective for the stated indications in pediatric patients (see Indications and Usage). As reported in the literature, the dosage selection and constant infusion rate of intravenous dextrose must be selected with caution in pediatric patients, particularly neonates and low birth weight infants, because of the increased risk of hyperglycemia/hypoglycemia. Frequent monitoring of serum glucose concentrations is required when dextrose is prescribed to pediatric patients, particularly neonates and low birth weight infants.

For patients receiving potassium supplement at greater than maintenance rates, frequent monitoring of serum potassium levels and serial EKGs are recommended.

Geriatric Use

Clinical studies of Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently

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from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Adverse Reactions

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

Dosage and Administration

As directed by a physician. Dosage is dependent upon the age, weight, and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Use of final filter is recommended during administration of all parenteral solutions, where possible. Do not administer unless solution is clear and seal is intact.

All injections in AVIVA plastic containers are intended for intravenous administration using sterile equipment.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

How Supplied

Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP in AVIVA plastic containers is available as shown below:

Code	Size (mL)	NDC	Product Name
6E2224	1000	NDC 0338-6344-04	20 mEq/L Potassium Chloride in Lactated

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16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055,
17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065,
17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029,
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Ringer's and 5%
Dextrose Injection, USP

6E2244	1000	NDC 0338-6345-04	40 mEq/L Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP
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Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure to up to 40°C does not adversely affect the product.

Directions for Use of AVIVA Plastic Container

To Open

Tear overwrap down side at slit and remove solution container. Moisture and some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

Caution: Do not use plastic containers in series connections.

Caution: Use only with a non-vented set or a vented set with the vent closed.

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Additives may be incompatible.

To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.

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6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

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* Bar Code Position Only

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