

## **PRODUCT MONOGRAPH**

### **Potassium Chloride Injection**

Sterile Solution

Potassium ion ( $K^+$ )

10 mEq/50mL, 20 mEq/50mL

10 mEq/100mL, 20 mEq/100mL

40mEq/100mL

Electrolyte Replenisher

Baxter Corporation  
Mississauga, Ontario L5N 0C2  
Canada

Date of Revision: October 25, 2012

Submission Control No.: 157615

## Table of Contents

<b>PART I: HEALTH PROFESSIONAL INFORMATION.....</b>	<b>3</b>
SUMMARY PRODUCT INFORMATION .....	3
INDICATIONS AND CLINICAL USE.....	3
CONTRAINDICATIONS .....	4
WARNINGS AND PRECAUTIONS.....	4
ADVERSE REACTIONS.....	6
DRUG INTERACTIONS .....	7
DOSAGE AND ADMINISTRATION.....	8
OVERDOSAGE .....	9
ACTION AND CLINICAL PHARMACOLOGY .....	10
STORAGE AND STABILITY.....	11
DOSAGE FORMS, COMPOSITION AND PACKAGING .....	11
<b>PART II: SCIENTIFIC INFORMATION .....</b>	<b>12</b>
PHARMACEUTICAL INFORMATION.....	12
DETAILED PHARMACOLOGY .....	12
TOXICOLOGY .....	13
REFERENCES .....	14
<b>PART III: CONSUMER INFORMATION.....</b>	<b>15</b>

# POTASSIUM CHLORIDE INJECTION

Potassium chloride

## PART I: HEALTH PROFESSIONAL INFORMATION

### SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form/Strength	Clinically Relevant Nonmedicinal Ingredients
Intravenous	Sterile solutions of : Potassium ion (K <sup>+</sup> ) 10 mEq/50mL (14.9mh/ml) 20 mEq/50mL (29.8mg/ml) 10 mEq/100mL (7.46mg/ml) 20 mEq/100mL (14.9mg/ml) 40mEq/100mL (29.8mg/ml)	There are no nonmedicinal ingredients. <i>For a complete listing see Dosage Forms, Composition and Packaging section.</i>

### INDICATIONS AND CLINICAL USE

This highly concentrated, ready-to-use potassium chloride injection is intended for the rapid correction of hypokalemia and for potassium supplementation in fluid restricted patients who cannot accommodate additional volumes of fluid associated with potassium solutions of lower concentration<sup>10, 11</sup>.

Potassium Chloride Injection is indicated for:

- treatment of potassium deficiency states where hypokalemia is severe<sup>6,7,8</sup>. Severe hypokalemia is defined as a serum potassium concentration of less than 2.5 mEq/L; serum potassium less than 3.0 mEq/L with definite symptoms or ECG signs of hypokalemia; or serum potassium less than 3.2 mEq/L in the presence of metabolic acidosis and treatment with sodium bicarbonate or insulin is imminent<sup>5</sup>.
- treatment of hypokalemia (K<sup>+</sup> < 3.5 mEq/L) in postoperative cardiothoracic surgical patients, where a serum potassium concentration of 4.0 to 5.0 mEq/L is necessary to minimize ventricular arrhythmias<sup>9</sup>.
- cautious treatment to abolish arrhythmias of cardiac glycoside toxicity precipitated by a loss of potassium. This regimen should not be used in patients with atrioventricular block<sup>1</sup>.

**Geriatrics (> 65 years of age):** No data are available.

**Pediatrics (≤16 years of age):** No data are available.

## CONTRAINDICATIONS

- Patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container. For a complete listing, see the DOSAGE FORMS, COMPOSITION, AND PACKAGING section of the Product Monograph.
- Hyperkalemia
- Renal impairment with oliguria, anuria or azotemia
- Untreated Addison's disease
- Ventricular fibrillation
- Salt-losing adrenal hyperplasia
- Extensive tissue breakdown as in severe burns, acute dehydration and heat cramps
- Increased sensitivity to potassium administration (e.g., in congenital paramyotonia or adynamia episodica hereditaria)
- Hyperadrenalism associated with adrenogenital syndrome<sup>3</sup>.
- Digitalis-induced second- or third-degree heart block is the only type of dysrhythmia in which potassium is contraindicated<sup>4</sup>.

## WARNINGS AND PRECAUTIONS

### Serious Warnings and Precautions

Potassium Chloride Injection should be administered with extreme caution, if at all, to patients with conditions predisposing to hyperkalemia and/or associated with increased sensitivity to potassium, such as patients with:

- potassium-aggravated skeletal muscle channelopathies (e.g., hyperkalemic periodic paralysis, paramyotonia congenita, and potassium-aggravated myotonia/paramyotonia).

Potassium Chloride Injection should be administered with caution to patients who are at risk of experiencing hyperosmolality, acidosis, or undergo correction of alkalosis (conditions associated with a shift of potassium from intracellular to extracellular space) and patients treated concurrently or recently with agents or products that can cause hyperkalemia (See Drug-Drug Interactions).

If used in high-risk patients, especially close monitoring and careful dose selection and adjustment is required.

## **General**

Potassium Chloride Injection should only be used in an ICU/CCU setting where a detailed protocol for administration of concentrated potassium chloride has been established. Uncontrolled infusion may lead to hyperkalemia.

In patients with impaired mechanisms for excreting potassium, administration of potassium chloride can produce hyperkalemia and cardiac arrest. This is of particular concern in patients given i.v. potassium. Potentially fatal hyperkalemia can develop rapidly and may be asymptomatic. To avoid potassium intoxication, do not infuse these solutions rapidly<sup>3</sup>. Patients must be kept on continuous cardiac monitoring and undergo frequent testing for serum potassium and acid-base balance, especially if they receive digitalis.

Administer intravenously only with a calibrated infusion device at a slow controlled rate (see DOSAGE AND ADMINISTRATION).

When infusing concentrated potassium solutions, care must be taken to prevent paravenous administration or extravasation because such solutions may be associated with tissue damage, which may be severe and may include vascular, nerve, and tendon damage and may lead to surgical intervention, including amputation. Secondary complications including pulmonary embolism from thrombophlebitis have been reported as a consequence of tissue damage from potassium chloride.

Administration via a central route is recommended for dilution by the blood stream and avoidance of extravasation<sup>2</sup>, as well as to avoid the pain and phlebitis associated with peripheral infusion. Correct placement of the catheter should be verified before administration.

The highest concentrations of Potassium Chloride Injection (300 mEq/L and higher) should be exclusively administered via central intravenous route.

Do not connect flexible plastic containers in series in order to avoid air embolism due to possible residual air contained in the primary container.

## **Cardiovascular**

Administration of concentrated potassium solutions can cause cardiac conduction disorders (including complete heart block) and other cardiac arrhythmias at any time during infusion. Use potassium with caution in disease associated with heart block since increased serum potassium may increase the degree of block<sup>3</sup>.

Patients requiring treatment of potassium depletion, particularly in the presence of cardiac disease, should be kept on continuous ECG monitoring and undergo clinical evaluation and frequent testing for serum potassium and acid-base balance. Continuous ECG monitoring is performed to aid in the detection of cardiac arrhythmias due to a sudden increase in serum potassium concentration (e.g., when potassium infusion is started), or transient or sustained hyperkalemia. Frequently, mild or moderate hyperkalemia is asymptomatic and may be

manifested only by increased serum potassium concentrations and, possibly, characteristic ECG changes. However, fatal arrhythmias can develop at any time during hyperkalemia.

### **Endocrine and Metabolism**

Use of potassium salts in patients with adrenal insufficiency or any other condition which impairs potassium excretion requires particularly appropriate dosage adjustment. See **Serious Warnings and Precautions**.

### **Renal**

Treatment of potassium depletion, particularly in the presence of renal disease or acidosis, requires careful attention to acid base balance and appropriate monitoring of serum electrolytes, the ECG and the patient's clinical status.

Use of potassium salts in patients with chronic renal disease or any other condition which impairs potassium excretion requires particularly appropriate dosage adjustment. See **Serious Warnings and Precautions**.

### **Special Populations**

**Pregnant Women:** Animal reproduction studies have not been conducted with potassium chloride, and there are no adequate data from the use of Potassium Chloride Injection in pregnant women. It is also not known whether potassium chloride can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Potassium chloride should be given to a pregnant woman only if clearly needed<sup>2</sup>, and after careful consideration of the potential risks and benefits.

**Nursing Women:** There are no adequate data from the use of Potassium Chloride Injection in lactating women. It is unknown if the drug is excreted in human milk. Because many drugs are excreted in human milk, the potential risks and benefits for each specific patient should be carefully considered before using Potassium Chloride Injection in lactating women.

**Pediatrics (< 16 years of age):** No data are available.

**Geriatrics (> 65 years of age):** No data are available.

### **Monitoring and Laboratory Tests**

Serum potassium levels are not necessarily indicative of tissue potassium levels. 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.

## **ADVERSE REACTIONS**

### **Adverse Drug Reaction Overview**

Potassium intoxication with mild or severe hyperkalemia has been reported. The signs and symptoms of intoxication include paresthesia of the extremities, areflexia, muscular or respiratory paralysis, mental confusion, weakness and heaviness of the legs, hypotension, cardiac arrhythmia, heart block, electrographic abnormalities and cardiac arrest. Hyperkalemia may exhibit the following ECG abnormalities: peaked T waves and a shortened QT interval when serum potassium exceeds 5.5 to 6.0 mEq/L; loss of P waves, widening of the QRS complex, and eventual asystole occurs with higher elevations<sup>5</sup>. Nausea, vomiting, abdominal pain and diarrhea have been reported with the use of potassium-containing solutions<sup>1</sup>.

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, and institute appropriate therapeutic countermeasures.

Pain associated with peripheral infusion of potassium chloride solution has been reported.

### **Post-Market Adverse Drug Reactions**

The following adverse reactions have been reported in the post-marketing experience. Events are listed by MedDRA System Organ Class (SOC), then by Preferred Term in order of severity, where feasible.

**Immune System Disorders:** Hypersensitivity, as manifested by rash and angioedema

**Metabolism And Nutrition Disorders:** Hyperkalemia

**Cardiac Disorders:** Cardiac arrest\*, Asystole\*, Ventricular fibrillation\*, Bradycardia

**Respiratory, Thoracic, And Mediastinal Disorders:** Dyspnea

**General Disorders And Administration Site Conditions:** Chest pain, Infusion site pain, Infusion site irritation, Burning sensation

### **Class Reactions**

Other adverse reaction associated with administration of concentrated potassium chloride solutions include:

In association with extravasation: Skin necrosis, Skin ulcer, Soft tissue necrosis, Muscle necrosis, Nerve injury, Tendon injury, and Vascular injury

Infusion site thrombosis, Infusion site phlebitis, Infusion site swelling, Infusion site erythema.

## **DRUG INTERACTIONS**

### **Overview**

---

\* as a manifestation of rapid intravenous administration and/or of hyperkalemia

Potassium Chloride Injection should be used with caution in patients treated concurrently or recently with agents or products that can cause hyperkalemia or increase the risk of hyperkalemia.

Administration of potassium in patients treated with such agents is associated with an increased risk of severe and potentially fatal hyperkalemia, in particular in the presence of other risk factors for hyperkalemia.

### **Drug-Drug Interactions**

<b>Name</b>	<b>Ref</b>	<b>Effect</b>	<b>Clinical Comment</b>
ACE Inhibitors	L	Concomitant administration can produce severe hyperkalemia	Use extreme caution if administering concomitantly
Potassium-sparing diuretics (e.g. amiloride, spironolactone, triamterene)	L	Concomitant administration can produce severe hyperkalemia	Use extreme caution if administering concomitantly

### **Drug-Food Interactions**

Interactions with food have not been established.

### **Drug-Herb Interactions**

Interactions with herbal products have not been established.

### **Drug-Laboratory Test Interactions**

Interactions with laboratory tests have not been established.

## **DOSAGE AND ADMINISTRATION**

### **Dosing Considerations**

The dose and rate of administration are dependent upon the specific condition of each patient.

### **Recommended Dose and Dosage Instructions**

Recommended administration rates should not usually exceed 10 mEq/hour or 200 mEq for a 24 hour period if the serum potassium level is greater than 2.5 mEq/L.

In urgent cases where the serum potassium level is less than 2.0 mEq/L or where severe hypokalemia is a threat, (serum potassium level less than 2.0 mEq/L and ECG changes and/or muscle paralysis) rates up to 40 mEq/hour or 400 mEq over a 24 hour period can be administered



very carefully when guided by continuous monitoring of the ECG and frequent serum K<sup>+</sup> determinations to avoid hyperkalemia and cardiac arrest.

### **Administration**

For intravenous use only. Administer only with a calibrated infusion device at a slow, controlled rate. The higher concentrations (300 mEq/L and higher) should be exclusively administered via central intravenous route. Because pain and phlebitis associated with peripheral infusion of potassium chloride solutions has been reported, administration via a central route for all concentrations is recommended for thorough dilution by the blood stream and avoidance of extravasation. Correct placement of the catheter should be verified before administration.

Parenteral drug products should be inspected visually for particulate matter and discoloration, whenever solution and container permit. Do not administer unless the solution is clear and the seal is intact. Use of a final filter is recommended during administration of all parenteral solutions where possible. Do not add supplementary medication<sup>2</sup>.

### **OVERDOSAGE**

**Symptoms:** If excretory mechanisms are impaired or if potassium is administered too rapidly i.v., potentially fatal hyperkalemia can result. Paresthesia of the extremities, listlessness, mental confusion, gastrointestinal symptoms (ileus, nausea, vomiting, abdominal pain), weakness, heaviness of legs, muscular and respiratory paralysis, hypotension, disturbances in cardiac conduction and arrhythmias, including bradycardia, heart block, asystole, ventricular tachycardia, ventricular fibrillation, and cardiac arrest may occur. Frequently, hyperkalemia is asymptomatic and may be manifested only by increased serum potassium concentration and, possibly, characteristic electrocardiographic changes. However, fatal arrhythmias can develop at any time.

In addition to arrhythmias and conduction disorders, progressive ECG changes occur with increasing potassium levels. Possible changes include peaking of T waves, loss of P waves, depression of S-T segment, and prolongation of the QT interval. Late manifestations include muscle paralysis and cardiovascular collapse from cardiac arrest. However, the correlation between potassium levels and ECG changes is not precise, and whether or at which potassium level certain ECG signs develop depends on factors such as patient sensitivity, the presence of other electrolyte disorders, and the rapidity of the development of hyperkalemia.

The presence of any ECG findings that are suspected to be caused by hyperkalemia should be considered a medical emergency.

**Treatment:** In the event that hyperkalemia is present or suspected, discontinue potassium i.v. administration immediately and institute corrective therapy to reduce serum potassium levels as necessary. The serum potassium concentration and ECG must be monitored, as well as serum electrolytes, creatinine, glucose and arterial blood gases.

Treatment of mild to severe hyperkalemia with signs and symptoms of potassium intoxication includes the following:

1. Elimination of potassium-rich foods, medications and i.v. solutions containing potassium, or medication which can induce hyperkalemia.

2. Dextrose Injection, USP, 10% or 25%, containing 10 units of crystalline insulin per 20 grams of dextrose administered intravenously, 300 to 500 mL per hour.
3. Correction of acidosis, if present, with 40-160 mEq of i.v. sodium bicarbonate infused over 5 minutes. This dose may be repeated after 10-15 minutes if ECG abnormalities persist.
4. Absorption and exchange of potassium using sodium or ammonium cycle cation exchange resin, orally and as retention enema.
5. Use of hemodialysis or peritoneal dialysis.
6. Use of Calcium gluconate. I.V. calcium is not recommended in patients receiving digoxin.

In treating hyperkalemia in digitalized patients, too rapid a lowering of the serum potassium concentration can produce digitalis toxicity<sup>1,2,4</sup>.

For management of a suspected drug overdose contact your regional Poison Control Centre.

## **ACTION AND CLINICAL PHARMACOLOGY**

### **Mechanism of Action**

Potassium is the major cation of intracellular fluid and is essential for maintenance of acid-base balance, isotonicity, and electrodynamic characteristics of the cell. Potassium is an important activator in many enzymatic reactions and is essential to a number of physiologic processes including transmission of nerve impulses; contraction of cardiac, smooth, and skeletal muscles; gastric secretion; renal function; tissue synthesis; and carbohydrate metabolism<sup>1</sup>. Chloride, the major extracellular anion, closely follows the metabolism of sodium, and changes in the acid-base of the body are reflected by changes in the chloride concentration.

Potassium first enters the extracellular fluid and is then actively transported into the cells. In healthy adults, serum potassium concentrations generally range from 3.5-5 mEq/L. Serum potassium concentrations, however, are not necessarily accurate indications of cellular potassium concentrations, as intracellular potassium accounts for 98% of total body amount. Potassium is excreted mainly by the kidneys. Normally about 80-90% of the potassium intake is excreted in the urine, the remainder in the stools and to a small extent, in the perspiration<sup>2</sup>.

Potassium depletion may occur whenever the rate of loss exceeds the rate of intake. Causes of hypokalemia include: inadequate intake, diuretic therapy, diabetic ketoacidosis, metabolic alkalosis, potassium-losing nephropathy, severe diarrhea, prolonged vomiting, drainage of gastrointestinal fluids, hyperaldosteronism, hepatic cirrhosis with ascites, Bartter's syndrome and long-term corticosteroid therapy. Potassium deficiency may cause vomiting, abdominal distention, malaise, myalgia, paralytic ileus, acute muscular weakness, paralysis, paresthesia, polydipsia and an inability to concentrate urine, cardiac arrhythmias, and coma<sup>3</sup>. Hypokalemia may also increase the toxicity of digoxin<sup>4</sup>. Severe potassium depletion (<2.5 mEq/L) may result in elevation of serum creatinine phosphokinase, aldolase, and aspartate aminotransferase levels.

Rhabdomyolysis may ensue when the serum potassium concentration falls below 2.0 mEq/L.

Chronic potassium depletion can lead to decreased glomerular filtration rate, renal blood flow, disturbance in tubular sodium handling, impairment of the urinary concentrating ability with polydipsia, and ADH-resistant nephrogenic diabetes insipidus. Reversible pathologic changes include renal hypertrophy and epithelial vacuolization of the proximal convoluted tubule. However, interstitial scarring and tubular atrophy have been reported with prolonged potassium depletion<sup>5</sup>.

## STORAGE AND STABILITY

Store at room temperature (15° to 25° C).

The ready to use VIAFLEX Plus plastic container is fabricated from a specially formulated polyvinyl chloride. Exposure to temperatures above 25°C during transport and storage will lead to minor losses in moisture content. Higher temperatures lead to greater losses. It is unlikely that these minor losses will lead to clinically significant changes within the expiration period. The amount of water that can permeate from inside the container into the overwrap is insufficient to affect the solution significantly. Solutions in contact with the plastic container may leach out certain of its chemical components from the plastic in very small amounts; however, biological testing was supportive of the safety of the plastic container materials.

## DOSAGE FORMS, COMPOSITION AND PACKAGING

Potassium Chloride Injection is a sterile nonpyrogenic solution of Potassium Chloride, USP in Water of Injection, USP intended for intravenous administration. It contains no antimicrobial agents, and is supplied in ready to use, single dose VIAFLEX Plus plastic (polyvinyl chloride) containers. The compositions of the various sizes and concentrations of Potassium Chloride Injection are as follows:

<b>Product Code No.</b>	<b>Pot. Chloride Inj. mEq. K<sup>+</sup>/Container</b>	<b>KCl Concentration</b>	<b>Potassium Chloride, USP</b>	<b>KCl, mg/ml</b>	<b>Water for Injection, USP</b>
JB0821	<b>10 mEq/50mL</b>	200 mEq/L	0.746 g	14.9mg/ml	q.s. to 50 mL
JB0826	<b>10 mEq/100mL</b>	100 mEq/L	0.746 g	7.46mg/ml	q.s. to 100 mL
JB0822	<b>20 mEq/50mL</b>	400 mEq/L	1.49 g	29.8mg/ml	q.s. to 50 mL
JB0827	<b>20 mEq/100mL</b>	200 mEq/L	1.49 g	14.9mg/ml	q.s. to 100 mL
JB0824	<b>40 mEq/100mL</b>	400 mEq/L	2.98 g	29.8mg/ml	q.s. to 100 mL

## PART II: SCIENTIFIC INFORMATION

### PHARMACEUTICAL INFORMATION

#### Drug Substance

Proper name: Potassium chloride, USP

Chemical name: Potassium chloride

Molecular formula and molecular mass: KCl; 74.55

Physicochemical properties: Potassium Chloride USP is a white crystalline powder having a melting point of 770 °C. It is freely soluble in water with a pH range of 4.0-8.0 at 25 °C.

### DETAILED PHARMACOLOGY

Potassium is the major cation of intracellular fluid and is essential for maintenance of acid-base balance, isotonicity and electrodynamic characteristics of the cell. Potassium is also essential in the physiological processes including nerve impulse transmission; contraction of cardiac, smooth and skeletal muscles; gastric secretion; renal function; tissue synthesis; and carbohydrate metabolism. In addition, potassium is an important activator in many enzymatic reactions<sup>1</sup>. Chloride is the major extracellular anion which is essential for the maintenance of acid-base balance.

#### Pharmacodynamics

*In vivo* studies performed were designed to evaluate the pharmacodynamics of concentrated potassium chloride administration to critically ill patients, pediatric cardiac surgical patients and cardiopulmonary bypass patients. According to Kruse and Carlson (1990), a positive correlation between the change in serum potassium level and the total dose administered was shown; however, there was only a modest linear correlation between differing hourly rates of potassium administration and change in serum potassium. An average increase in serum potassium level of 0.25 mmol/L per 20 mEq infusion was observed. There was not a clear relationship between changes in potassium and serum creatinine level.<sup>7</sup>

The dose-response curve observed by Schaber et al. had a very low coefficient of determination. Eighty-seven percent of responses were an increase in serum potassium. The variability in response to a given dose was expected due to the complex interaction of the physiologic variables involved such as: the dose administered, arterial pH, pre-infusion serum potassium concentration, and serum bicarbonate concentration. A preinfusion serum potassium less than or equal to 3.5 mEq/L was associated with a change in serum potassium of  $0.79 \pm 0.23$  mEq/kg. Patients with a preinfusion serum potassium less than 3.5 mEq/L received a slightly greater potassium dose than those with a higher preinfusion serum concentration. If the preinfusion serum potassium was greater than 3.5 mEq/L, the change in serum potassium was  $0.51 \pm 0.48$  mEq/L<sup>11</sup>.

Manning et al. (1982) observed that there was only a modest linear correlation between differing hourly rates of potassium administration and change in serum potassium. The mean change in

serum potassium after 33.0 mmol of potassium chloride was  $0.40 \pm 0.42$  mmol/L<sup>9</sup>.

### Dose Response Data

Study Author	Pre-infusion Serum [K <sup>+</sup> ]	Mean Change in Serum Potassium
Kruse and Carlson, 1990	3.22 mmol/L	0.25 mmol/L for each 20 mEq administered
Manning et al. 1982	$3.6 \pm 0.28$ mmol/L	$0.40 \pm 0.45$ mmol/L after administration of 33.0 mEq
Schaber et al. 1985	$\leq 3.5$ mEq/L $\geq 3.5$ mEq/L	$0.79 \pm 0.44$ mEq/L after administration of $0.78 \pm 0.27$ mEq/kg $0.51 \pm 0.48$ mmol/L after administration of $0.69 \pm 0.19$ mEq/kg

### Pharmacokinetics

#### Distribution

Potassium first enters the extracellular fluid and is then actively transported into the cells where its concentration is up to 40 times that outside the cell. According to Kruse et al. (1994), the kinetic behaviour of potassium demonstrated a maximum plasma concentration at the end of the infusion. This maximum concentration decreased rapidly postinfusion and stabilized.

Manning et al. (1982) reported no significant or consistent changes that would indicate a distribution phase.

#### Elimination

Potassium is excreted mainly by the kidneys. The cation is filtered by the glomeruli, reabsorbed in the proximal tubule, and secreted in the distal tubule, the site of sodium-potassium exchange. Tubular secretion of potassium is also influenced by chloride ion concentration, hydrogen ion exchange, acid-base equilibrium, and adrenal hormones. Surgery and/or tissue injury result in increased urinary excretion of potassium which may continue for several days. Small amounts of potassium may be excreted via the skin and intestinal tract, but most of the potassium excreted into the intestine is later reabsorbed.

Manning et al. (1982) reported that in postoperative cardiopulmonary bypass patients who were administered intermittent concentrated potassium chloride, a mean potassium intake of  $37.4 \pm 4.7$  mmols resulted in a mean urine potassium excretion of  $29.4 \pm 19$  mmols.

### TOXICOLOGY

The potential toxic side effects of potassium chloride have been characterized through extensive clinical use for many years. Potassium chloride is a well-characterized drug. The medical literature documents the use of concentrated potassium chloride injection and no occurrence of unusual side effects has been noted when proper administration procedures are followed.

## REFERENCES

1. AHFS Drug Information 96: Potassium Supplements. American Society of Health-System Pharmacists, Bethesda, 1996: 1871-1876.
2. Potassium Chloride Injection Product Insert. Baxter Healthcare Corporation, Deerfield, USA, 1996.
3. Potassium Salts, General Monograph. CPS 32ed. Canadian Pharmaceutical Association, Toronto, 1997: 1258-1259.
4. Principles of Medical Pharmacology, 5th ed. B.C. Decker Inc., Toronto, 1989: 349.
5. Applied Therapeutics: The Clinical Use of Drugs, 6th ed. Applied Therapeutics Inc., Vancouver, 1995.
6. Singhi S, Gautham KS, Lal A. Safety and Efficacy of a Concentrated Potassium Chloride Solution Infusion for Rapid Correction of Hypokalemia. *Indian Pediatrics*, 1994; 31: 565-569.
7. Kruse JA, Carlson RW. Rapid correction of hypokalemia using concentrated intravenous potassium chloride infusions. *Archs Intl Med*. 1990;150: 613-7.
8. Stanaszek WR et al. Current approaches to management of potassium deficiency. *Drug Intell Clin Pharm*. 1985;19:176-183.
9. Manning SM, Angaran DM, Arom KV et al. Intermittent intravenous potassium therapy in cardiopulmonary bypass patients. *Clin Pharm*. 1982;1:234-8.
10. Kruse JA, Clark VL, Carlson RW et al. Concentrated potassium chloride iInfusion in critically ill patients with hypokalemia. *J Clin Pharmacol*. 1994; 34:1077-82.
11. Schaber DE, Uden DL, Stone FM et al. Intravenous KCl: Supplementation in pediatric cardiac surgical patients. *Ped Cardiol*. 1985; 6: 25-8.
12. Cohen MR. Ongoing potassium chloride concentrate errors kill patients: An issue of cost versus care? *Hospital Pharmacy*. 1996; 31(2): 187-8.

## PART III: CONSUMER INFORMATION

### Highly Concentrated Potassium Chloride Injection

Sterile Injection

Potassium ion (K<sup>+</sup>)

10 mEq/50mL, 20 mEq/50mL

10 mEq/100mL, 20 mEq/100mL, 40mEq/100mL)

Electrolyte Replenisher

**This leaflet is part III of a three-part "Product Monograph" published when Potassium Chloride Injection was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Potassium Chloride Injection. Contact your doctor or pharmacist if you have any questions about the drug.**

### ABOUT THIS MEDICATION

#### What the medication is used for:

Potassium Chloride Injection is administered by a Health care Professional to treat potassium deficiency. This means that your body does not have the blood level of potassium that it needs to work properly.

#### What it does:

Potassium chloride replacement will add potassium to your body.

#### When it should not be used:

Potassium Chloride Injection should not be used if:

- you have a hypersensitivity to potassium or to any component of the container (plastic; polyvinyl chloride)
- you already have too much potassium in your body (hyperkalemia)
- you have kidney (renal) impairment
- you have untreated Addison's disease (a condition in which your adrenal glands do not make enough of certain hormones)
- you have irregular heart rhythm (ventricular fibrillation)
- you have a genetic condition of the adrenal gland (salt-losing adrenal hyperplasia)
- you have extensive tissue damage such as severe burns, acute dehydration and heat cramps
- you have increased sensitivity to potassium administration

- you have an overactive adrenal gland (hyperadrenalism associated with adrenogenital syndrome)
- you have abnormal heart rhythm while taking digitalis that leads to heart block (digitalis induced second and third degree heart block)

#### What the medicinal ingredient is:

Potassium Chloride

#### What the important nonmedicinal ingredients are:

There are no non-medicinal ingredients in Potassium Chloride Injection.

#### What dosage forms it comes in:

Potassium Chloride Injection comes as a sterile solution for intravenous administration. It is available in the following strengths and volumes: Potassium ion (K<sup>+</sup>) 10 mEq/50mL, 10 mEq/100mL, 20 mEq/50mL, 20 mEq/100mL, 40 mEq/100mL.

### WARNINGS AND PRECAUTIONS

#### **Serious Warnings and Precautions**

If you have a condition that makes it more likely that you will already have too much potassium in your system or if you have a condition that makes you more sensitive to serum potassium levels, Potassium Chloride Injection must be given to you with extreme caution. Some examples of conditions that would put you at risk include:

- muscle disorders such as potassium-aggravated skeletal muscle channelopathies (e.g., hyperkalemic periodic paralysis, paramyotonia congenita, and potassium-aggravated myotonia/paramyotonia).

Potassium Chloride Injection will be administered with caution to you if you are at risk of experiencing hyperosmolality (high concentration of salts in the blood), acidosis (too much acid in the blood), or undergo correction of alkalosis (conditions associated with a shift of potassium from intracellular to extracellular space) or if you are receiving (or recently received) treatment with agents or products that can cause you to have too much potassium in your system (See **Interactions**).

Your doctor will monitor your condition.

BEFORE you use Potassium Chloride Injection, talk to your doctor or pharmacist if:

- You have any of the following conditions:
  - Heart problems, such as congestive

- heart failure or problems with the rate or rhythm of your heart beat
- Kidney problems
- Problems with your adrenal gland (e.g. Addison's disease)
- You are pregnant
- You are nursing an infant

### INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with Potassium Chloride Injection include:

- Diuretics that may prevent loss of potassium, such as amiloride spironolactone, triamterene and Medications used to treat high blood pressure such as Angiotensin Converting Enzyme (ACE) inhibitors

### PROPER USE OF THIS MEDICATION

#### Usual Dose:

The appropriate dose is selected by the Health Care Professional and is administered through a vein.

#### Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

#### Missed Dose:

If you miss your scheduled infusion, contact your doctor or nurse as soon as possible to schedule your next treatment.

### SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The side effects reported with Potassium Chloride Injection may be a result of how the product has been given to you (such as pain or infection at the infusion site, fever). Most often, the side effects that occur are a result of your body responding to the increased levels of potassium in your system.

### SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM

- Pain at the infusion site
- Burning at the infusion site
- Swelling at the infusion site
- Nausea
- Vomiting
- Diarrhea
- Numbness in hands or feet
- Difficulty breathing
- Changes in heart rate or heart rhythm
- Rash or swelling

**Talk with your doctor or pharmacist in all cases**

*This is not a complete list of side effects. For any unexpected effects while taking Potassium Chloride Injection, contact your doctor or pharmacist.*

### HOW TO STORE IT

Store at room temperature (15° to 25° C).



## **REPORTING SUSPECTED SIDE EFFECTS**

**You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:**

-----

- **Report online at**  
**[www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)**
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
  - **Fax toll-free to 1-866-678-6789, or**
  - **Mail to: Canada Vigilance Program**  
**Health Canada**  
**Postal Locator 0701D**  
**Ottawa, Ontario**  
**K1A 0K9**

**Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect).**

***NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.***

## **MORE INFORMATION**

This document plus the full product monograph, prepared for health professionals can be obtained by contacting the sponsor, Baxter Corporation, at:

1-800-387-8399

This leaflet was prepared by Baxter Corporation, Mississauga, ON L5N 0C2

Last revised: October 25, 2012