

1.5% Glycine Irrigation, USP in UROMATIC Plastic Container

DESCRIPTION

1.5% Glycine Irrigation, USP is a sterile, nonpyrogenic, nonhemolytic, nonelectrolytic or very weakly ionized solution in single dose UROMATIC containers for use as a urologic irrigating solution. Each liter contains 15 g Glycine, USP ($\text{NH}_2\text{CH}_2\text{COOH}$) in water for injection. pH 6.0 (4.5 to 6.5). Osmolarity 200 mOsmol/L (calc.). Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L. No antimicrobial agent has been added.

The UROMATIC plastic container is fabricated from a specially formulated polyvinyl chloride (PL 146 plastic). 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 can leach out certain of its chemical components in very small amounts within the expiration period, e.g., di-2-ethylhexyl phthalate (DEHP), up to 5 parts per million; however, the safety of the plastic has been confirmed in tests in animals according to USP biological tests for plastic containers as well as by tissue culture toxicity studies.

CLINICAL PHARMACOLOGY

1.5% Glycine Irrigation, USP is useful as an irrigating solution for the urinary bladder because this solution is nonhemolytic, nonelectrolytic or very weakly ionized, and provides a high degree of visibility for urologic procedures requiring endoscopy. During transurethral surgical procedures, the solution acts as a lavage for removing blood and tissue fragments. It also maintains the patency of an indwelling catheter in the immediate postoperative period.

Glycine which enters the systemic circulation is converted to serine and glyoxylic acid.

INDICATIONS AND USAGE

1.5% Glycine Irrigation, USP is indicated for use as a urologic irrigating fluid with endoscopic instruments during transurethral procedures requiring distension, irrigation, and lavage of the urinary bladder. It may be used for lavage of an indwelling catheter to maintain patency.

CONTRAINDICATIONS

Anuria.

WARNINGS

Not for injection.

Solutions for urologic irrigation must be used with caution in patients with severe cardiopulmonary or renal dysfunction.

Irrigating fluids used during transurethral prostatectomy have been demonstrated to enter the systemic circulation in relatively large volumes; thus 1.5% Glycine Irrigation, USP must be regarded as a systemic drug. Absorption of large amounts of fluids containing glycine may significantly alter cardiopulmonary and renal dynamics.

Careful cardiovascular monitoring should be maintained due to the possibility of fluid overload. Should fluid overload occur, intensive fluid and electrolyte management is necessary. Monitoring of fluid and electrolyte levels beyond the acute phase may be considered due to the possibility of delayed fluid absorption. (See ADVERSE REACTIONS, Post-Marketing Experience).

The contents of an opened container should be used promptly to minimize the possibility of bacterial growth or pyrogen formation. Discard the unused portion of irrigating solution since no antimicrobial agent has been added.

PRECAUTIONS

The cardiovascular status, especially of the patient with cardiac disease, should be carefully observed before and during transurethral resection of the prostate when using 1.5% Glycine Irrigation, USP, because the quantity of fluid absorbed into the systemic circulation by opened prostatic veins may produce significant expansion of the intravascular fluid and lead to fulminating congestive heart failure.

Shift of sodium-free intracellular fluid into the extracellular compartment, following systemic absorption, may lower serum sodium concentration and aggravate preexisting hyponatremia.

Care should be exercised if impaired liver function is known or suspected. Under such conditions ammonia resulting from metabolism of glycine may accumulate in the blood.

Pregnancy - Teratogenic Effects

Animal reproduction studies have not been conducted with 1.5% Glycine Irrigation, USP. It is not known whether 1.5% Glycine Irrigation, USP can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. 1.5% Glycine Irrigation, USP should be given to a pregnant woman only if clearly needed.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

Clinical studies of Irrigation Solutions did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from other younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients.

Do not administer unless the solution is clear and the seal is intact.

ADVERSE REACTIONS

Adverse reactions may result from intravascular absorption of glycine. Large intravenous doses of glycine are known to cause salivation, nausea and lightheadedness. Other consequences of absorption of urologic irrigating solutions include fluid and electrolyte disturbances such as acidosis, electrolyte loss, marked diuresis, urinary retention, edema, dryness of mouth, thirst, dehydration, coma from hyponatremia, secondary hyponatremia due to fluid overload, and hyperammonemia with resultant coma and/or encephalopathy; cardiovascular disorders such as hypotension, tachycardia, angina-like pains; pulmonary disorders such as pulmonary congestion; and other general reactions such as blurred vision, convulsions, nausea, vomiting, rhinitis, chills, vertigo, backache, transient blindness and urticaria. Allergic reactions from glycine are unknown or exceedingly rare.

Should adverse reactions occur, discontinue the irrigation and re-evaluate the clinical status of the patient.

Post-Marketing Experience

Following off-label use of 1.5% Glycine Irrigation, USP for hysteroscopic procedures in women, life-threatening adverse events related to fluid overload have been reported.

OVERDOSAGE

In the event of overhydration or solute overload, re-evaluate the patient and institute appropriate corrective measures. See WARNINGS, PRECAUTIONS and ADVERSE REACTIONS.

DOSAGE AND ADMINISTRATION

The volume of solution needed will vary with the nature and duration of the urologic procedure.

If desired, warm in overwrap to near body temperature in a water bath or oven heated to not more than 45°C.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

HOW SUPPLIED 1.5% Glycine Irrigation, USP in UROMATIC plastic containers is available as follows:

2B7317 3000mL NDC 0338-0289-47

Color variation in this product is normal and does not alter efficacy or visualization during TUR procedures.

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

Tear overwrap down side at slit and remove solution container. Visually inspect the container. If the outlet port protector is damaged, detached, or not present, discard container as solution path sterility may be impaired. 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 bag firmly. If leaks are found, discard solution as sterility may be impaired.

Use Aseptic Technique.

1. Suspend container using hanger hole.
2. Remove protector from outlet port.
3. Attach irrigation set. Refer to complete directions accompanying set.

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