

1.5% GLYCINE IRRIGATION, USP

NONELECTROLYTE IRRIGATING FLUID FOR TRANSURETHRAL SURGICAL PROCEDURES.

**For Urologic Irrigation Only; Not For Injection By Usual Parenteral Routes
Flexible Irrigation Container**

Rx only

DESCRIPTION

1.5% Glycine Irrigation, USP is a sterile, nonpyrogenic, hypotonic, aqueous solution of glycine intended only for urologic irrigation during transurethral surgical procedures.

Each 100 mL contains 1.5 g of glycine in water for injection. The solution is nonelectrolytic, hypotonic and has an osmolarity of 200 mOsmol/liter (calc.); pH 6.0 (4.5 to 6.5).

The solution contains no bacteriostat, antimicrobial agent or added buffer and is intended only for use as a single-dose irrigation. When smaller volumes are required, the unused portion should be discarded.

1.5% Glycine Irrigation is a urologic nonelectrolyte irrigant.

Glycine, USP is chemically designated aminoacetic acid (C₂H₅NO₂), a white crystalline powder freely soluble in water. It has the following structural formula:



Water for Injection, USP is chemically designated H₂O.

The flexible plastic container is fabricated from a specially formulated polyvinylchloride. Water can permeate from inside the container into the overwrap but not in amounts sufficient to affect the solution significantly.

The semi-rigid container is fabricated from a specially formulated polyolefin. It is a copolymer of ethylene and propylene. The container requires no vapor barrier to maintain the proper drug concentration.

The flexible plastic container is fabricated from a specially formulated polyvinylchloride. Water can permeate from inside the container into the overwrap but not in amounts sufficient to affect the solution significantly. Solutions in contact with the plastic container may leach out certain chemical components from the plastic in very small amounts; however, biological testing was supportive of the safety of the plastic container materials. Exposure to temperatures above 25°C/77°F 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.

CLINICAL PHARMACOLOGY

Glycine is an amino acid and a nonelectrolyte. A solution of glycine in water is therefore nonconductive and suitable for urologic irrigation during electrosurgical procedures. A 1.5% concentration of glycine in water (200 mOsmol/liter calc.) is sufficient to minimize the risk of intravascular hemolysis which can occur from absorption of plain water through open prostatic veins during transurethral resection (TUR). It is hypotonic in relation to the extracellular fluid (280 mOsmol/liter). Any solution absorbed intravascularly during transurethral prostatic or bladder surgery, although variable in amount depending primarily on the extent of surgery, will be excreted

by the kidney. Studies have shown that the absorption of glycine does not cause significant hemolysis (increase of free hemoglobin) or release significant amounts of free ammonia in the blood. Glycine is rapidly degraded in the liver by glycine oxidase.

Water is an essential constituent of all body tissues and accounts for approximately 70% of total body weight. Average normal adult daily requirement ranges from two to three liters (1.0 to 1.5 liters each for insensible water loss by perspiration and urine production).

Water balance is maintained by various regulatory mechanisms. Water distribution depends primarily on the concentration of electrolytes in the body compartments and sodium (Na⁺) plays a major role in maintaining physiologic equilibrium.

INDICATIONS AND USAGE

1.5% Glycine Irrigation, USP is indicated for use as irrigating fluid during transurethral prostatic resection and other transurethral surgical procedures.

CONTRAINDICATIONS

NOT FOR INJECTION BY USUAL PARENTERAL ROUTES.

Do not use in patients with anuria.

WARNINGS

FOR UROLOGIC IRRIGATION ONLY.

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, glycine irrigating solution must be regarded as a systemic drug. Absorption of large amounts of fluids containing glycine may significantly alter cardiopulmonary and renal dynamics.

Do not heat container over 66°C (150°F).

PRECAUTIONS

Cardiovascular status, especially of the patient with cardiac disease, should be carefully observed before and during transurethral resection of the prostate when using glycine irrigating solution, because the quantity of fluid absorbed into the systemic circulation by opened prostatic veins may produce significant expansion of the extracellular fluid and lead to fulminating congestive heart failure. Shift of sodium free intracellular fluid into the extracellular compartment following systemic absorption of solution may lower serum sodium concentration and aggravate pre-existing 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.

Aseptic technique is essential with the use of sterile solutions for irrigation. The administration set should be attached promptly. Unused portions should be discarded and a fresh container of appropriate size used for the start-up of each cycle or repeat procedure.

Do not administer unless solution is clear, seal is intact and container is undamaged. Discard unused portion.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Studies with Glycine Irrigation, USP have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Nursing Mothers: Caution should be exercised when Glycine Irrigation, USP is administered to a nursing woman.

Pregnancy: Teratogenic Effects.

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

Pediatric Use: The safety and effectiveness of Glycine Irrigation have not been established. Its limited use in pediatric patients has been inadequate to fully define proper dosage and limitations for use.

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 any adverse reaction occur, discontinue the irrigant, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

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

1.5% Glycine Irrigation, USP should be administered only by transurethral instillation with appropriate urologic instrumentation. A disposable irrigation set should be used. The total volume of solution used for irrigation is solely at the discretion of the surgeon.

Height of container(s) above the operating table in excess of 60 cm (approx. 2 ft.) has been reported to increase intravascular absorption of the irrigating fluid.

Drug Interactions

Additives may be incompatible. Consult with pharmacist, if available. When introducing additives, use aseptic technique, mix thoroughly and do not store.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution container permits. See PRECAUTIONS.

HOW SUPPLIED

1.5% Glycine Irrigation, USP is supplied in single-dose 3000 mL flexible irrigation container (List No. 7974).

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. Protect from freezing. Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.]

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