5% Dextrose and 0.45% Sodium Chloride Injection, USP

VISIV™ Container

℞ only

DESCRIPTION

5% Dextrose and 0.45% Sodium Chloride Injection, USP solution is sterile and nonpyrogenic. It is a large volume parenteral solution containing dextrose and sodium chloride in water for injection intended for intravenous administration.

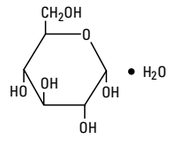
Each 100 mL of 5% Dextrose and 0.45% Sodium Chloride Injection, USP contains dextrose, hydrous 5 g and sodium chloride 0.45 g in water for injection. Electrolytes per 1000 mL: sodium (Na^+), 77 mEq; chloride (Cl^-) 77 mEq. The osmolarity is 406 mOsmol/L (calc.), which is hypertonic. The caloric value is 170 kcal/L.

The pH is 4.3 (3.5 to 6.5).

5% Dextrose and 0.45% Sodium Chloride Injection, USP contains no bacteriostat, antimicrobial agent or added buffer and is intended only as a single-dose injection. When smaller doses are required, the unused portion should be discarded.

5% Dextrose and 0.45% Sodium Chloride Injection, USP is a parenteral fluid, nutrient and electrolyte replenisher.

Dextrose, USP is chemically designated D-glucose monohydrate ($C_6H_{12}O_6 \cdot H_2O$), a hexose sugar freely soluble in water. It has the following structural formula:



Sodium Chloride, USP is chemically designated NaCl, a white crystalline powder freely soluble in water.

Water for Injection, USP is chemically designated H_20.

The flexible plastic container is fabricated from a clear multilayer plastic film (FC97). 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

When administered intravenously, these solutions provide a source of water, carbohydrate and electrolytes.

Solutions which provide combinations of hypotonic or isotonic concentrations of dextrose and of sodium chloride are suitable for parenteral maintenance or replacement of water and electrolyte requirements with minimal carbohydrate calories.

Solutions containing carbohydrate in the form of dextrose restore blood glucose levels and provide calories. Carbohydrate in the form of dextrose may aid in minimizing liver glycogen depletion and exerts a protein-sparing action. Dextrose injected parenterally undergoes oxidation to carbon dioxide and water.

Sodium chloride in water dissociates to provide sodium (Na^+) and chloride (Cl^-) ions. Sodium (Na^+) is the principal cation of the extracellular fluid and plays a large part in the therapy of fluid and electrolyte disturbances. Chloride (Cl^-) has an integral role in buffering action when oxygen and carbon dioxide exchange occurs in the red blood cells. The distribution and excretion of sodium (Na^+) and chloride (Cl^-) are largely under the control of the kidney which maintains a balance between intake and output.

Water is an essential constituent of all body tissues and accounts for approximately 70% of total body weight. Average normal adult daily requirements range 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

Intravenous solutions containing dextrose and sodium chloride are indicated for parenteral replenishment of fluid, minimal carbohydrate calories, and sodium chloride as required by the clinical condition of the patient.

CONTRAINDICATIONS

None known.

WARNINGS

Solutions containing sodium ions 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.

Excessive administration of potassium-free solutions may result in significant hypokalemia.

In patients with diminished renal function, administration of solutions containing sodium ions may result in sodium retention.

The intravenous administration of these solutions 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 administered parenteral solutions. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of such solutions.

PRECAUTIONS

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.

Solutions containing dextrose should be used with caution in patients with known subclinical or overt diabetes mellitus.

Caution must be exercised in the administration of parenteral fluids, especially those containing sodium ions to patients receiving corticosteroids or corticotropin.

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

Pregnancy: Teratogenic effects

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

Pediatric Use. The safety and effectiveness in the pediatric population are based on the similarity of the clinical conditions of the pediatric and adult populations. In neonates or very small infants, the volume of fluid may affect fluid and electrolyte balance. Frequent monitoring of serum glucose concentrations is required when dextrose is prescribed to pediatric patients, particularly neonates and low birth weight infants.

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

Geriatric Use. An evaluation of current literature revealed no clinical experience identifying differences in response 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 other drug therapy. Sodium ions are known to be substantially excreted by the kidney, and the risk of toxic reactions 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.

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 dose is dependent upon the age, weight and clinical condition of the patient.

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 birth weight infants, because of the increased risk of hyperglycemia/hypoglycemia.

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

Drug Interactions

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

INSTRUCTIONS FOR USE

Check for leaks by squeezing container firmly. If leaks are found, discard unit as sterility may be impaired. If supplemental medication is desired, follow directions below before preparing for administration.

To Add Medication
(Use aseptic technique)

1. Remove blue cap from sterile medication additive port at bottom of container.
2. With a needle of appropriate length, puncture resealable additive port and inject. Withdraw needle after injecting medication.
3. Mix container contents thoroughly.
4. The additive port may be protected by an appropriate cover.

Preparation for Administration
(Use aseptic technique)

NOTE: See appropriate I.V. administration set Instructions for Use.

1. Close flow control clamp of administration set.
2. Remove cap from sterile administration set port at bottom of container.
3. Insert piercing pin of administration set into port with a twisting motion until the pin is firmly seated.
4. Suspend container.
5. Squeeze and release drip chamber to establish proper fluid level in chamber.
6. Open clamp. Eliminate air from remainder of set.
7. Attach set to patient access device.
8. Begin infusion.

WARNING: Do not use flexible container in series connections.

HOW SUPPLIED

5% Dextrose and 0.45% Sodium Chloride Injection, USP is supplied in single-dose flexible plastic containers as follows:

List No.	Product Name	Container Size (mL)
7926	5% Dextrose and 0.45% Sodium Chloride Injection, USP	500 & 1000

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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