5% Dextrose & 0.45% Nacl - NPVC

120 x 200 mm Side A

Dextrose 5% in 0.45%
Sodium Chloride Injection
Solution for Infusion in Non PVC Bags

DESCRIPTION

Dextrose 5% in 0.45% Sodium Chloride Injection 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 nominal (range)	Ionic Concentration (mEq/L)		Caloric Content (kcal/L)
		Dextrose Monohydrate	Sodium Chloride, (NaCl)			Sodium	Chloride	
5% Dextrose and 0.45% Sodium Chloride Injection	500 1000	50	4.5	406	4.0	77	77	170

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

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.

DESCRIPTION OF THE PRIMARY BAGS:

Type and size: Non PVC plastic bag + overpouch; size: 500 ml and 1000 ml.

Material composition:

- Non PVC plastic film, based on polyethylene, polyamide, and polypropylene.
- Overpouch based on co-extruded blend: polypropylene/polyamide/polypropylene film.

CLINICAL PHARMACOLOGY

Dextrose 5% in 0.45% Sodium Chloride Injection 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 5% in 0.45% Sodium Chloride Injection is indicated to provide electrolytes and calories and as a source of water for hydration.

CONTRAINDICATIONS

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

WARNINGS

Dextrose 5% in 0.45% Sodium Chloride Injection 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 intravenous administration of Dextrose 5% in 0.45% Sodium Chloride Injection 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 5% in 0.45% Sodium Chloride Injection may result in significant hypokalemia.

In patients with diminished renal function, administration of Dextrose 5% in 0.45% Sodium Chloride Injection may result in sodium retention.

PRECAUTIONS

General

Do not connect flexible plastic containers of intravenous solutions in series 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 5% in 0.45% Sodium Chloride Injection should be used with caution in patients with overt or subclinical diabetes mellitus.

Administration of hypertonic solutions may cause venous irritation, including phlebitis. Hyperosmolar solutions should be administered with caution, if at all, to patients with hyperosmolar states. See **Table 1** in the **DESCRIPTION** section for the osmolarities of the Dextrose and Sodium Chloride Injection solutions.

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 Dextrose and Sodium Chloride Injection 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.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies with Dextrose and Sodium Chloride Injection 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. It is also not known whether Dextrose and Sodium Chloride Injection can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Dextrose and Sodium Chloride Injection 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 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 is administered to a nursing mother.

Pediatric Use

The use of Dextrose and Sodium Chloride Injection, USP in pediatric patients is based on clinical practice.

Newborns - especially those born premature and with low birth weight - are at increased risk of developing

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120 x 200 mm Side B

hypo- or hyperglycemia and therefore need close monitoring during treatment with intravenous glucose solutions to ensure adequate glycemic control in order to avoid potential long term adverse effects. Hypoglycemia in the newborn can cause prolonged seizures, coma and brain damage. Hyperglycemia has been associated with intraventricular hemorrhage, late onset bacterial and fungal infection, retinopathy of prematurity, necrotizing enterocolitis, bronchopulmonary dysplasia, prolonged length of hospital stay, and death.

Plasma electrolyte concentrations should be closely monitored in the pediatric population as this population may have impaired ability to regulate fluids and electrolytes.

The infusion of hypotonic fluids together with the non-osmotic secretion of ADH may result in hyponatremia in patients with acute volume depletion. Hyponatremia can lead to headache, nausea, seizures, lethargy, coma, cerebral oedema and death, therefore acute symptomatic hyponatremic encephalopathy is considered a medical emergency (applies to solutions containing less than 0.9% Sodium Chloride).

Geriatric Use

Clinical studies of Dextrose and Sodium Chloride Injection 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 other 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

- Hypersensitivity reactions, including anaphylaxis and chills
- Hyponatremia

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.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form:

http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

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 plastic containers are intended for intravenous administration using sterile equipment.

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. The infusion rate and volume depends on the age, weight, clinical and metabolic conditions of the patient, concomitant therapy and should be determined by the consulting physician experienced in pediatric intravenous fluid therapy.

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 5% in 0.45% Sodium Chloride Injection in Non PVC plastic container is supplied in 500 ml and 1000 ml bags.

Storage

It is recommended that the product be stored below 25°C.

Shelf life

Unopened product: 24 months

DIRECTIONS FOR USE OF PLASTIC CONTAINER

Do not remove units from overwrap until ready for use. Use all units promptly when pouch is opened.

To Open

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. 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 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.

REGISTRATION NUMBER

038.88.22826.00

MANUFACTURER

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