10% Dextrose Injection
(Dextrose in Water) in Plastic Bags.

INTRAVENOUS INJECTION / PARENTERAL NUTRIENT

Description
10% Dextrose Injection is a solution of Dextrose 10% in Water. It can be used either:
(a) As Intravenous solution for fluid replenishment and caloric supply in single dose container for intravenous administration, or
(b) As parenteral nutrient.

10% Dextrose Injection is a sterile, nonpyrogenic, hypertonic solution. It contains no antimicrobial or buffering agents.

Composition, osmolarity, pH value and caloric content are as follows:

<table>
<thead>
<tr>
<th>Composition</th>
<th>Dextrose monohydrate 100g/L</th>
</tr>
</thead>
<tbody>
<tr>
<td>Osmolarity</td>
<td>505 mOsm/L</td>
</tr>
<tr>
<td>Approximate pH value</td>
<td>4.0</td>
</tr>
<tr>
<td>Caloric content</td>
<td>340 Kcal/L</td>
</tr>
</tbody>
</table>

The plastic bag is fabricated from a specially formulated polyvinyl chloride. Water can permeate from inside the bag into the overwrap in amounts insufficient to affect the solution significantly. Solutions in contact with the plastic bag can leach out certain of its chemical components in very small amounts, however, testing was supportive of the safety of the plastic container materials.

Clinical Pharmacology
10% Dextrose injection has a value as a source of water and calories. It is capable of inducing diuresis depending on the clinical condition of the patient.
For caloric value see second table above.

Indications
As Intravenous Injection
10% Dextrose Injection is indicated as a source of water and calories.

As Parenteral Nutrient
10% Dextrose Injection is indicated as a caloric component in a parenteral nutrition regimen. It is used with an appropriate protein (nitrogen) source in the prevention of nitrogen loss or in the treatment of negative nitrogen balance in patients where:
(1) the alimentary tract cannot or should not be used
(2) gastrointestinal absorption of protein is impaired, or
(3) metabolic requirements for protein are substantially increased, as with extensive burns.
Use in Pregnancy
Animal reproduction studies have not been conducted with Dextrose Injections. It is also not known whether these solutions can cause fetal harm when administered to a pregnant woman, or can affect reproduction capacity. Dextrose injections should be given to a pregnant woman only if clearly needed.

Use in Pediatrics
This product should be used with caution in infants of diabetic mothers, except as may be indicated in hypoglycemic neonates.

Overdosage
In the event of fluid or solute overload during parenteral fluids, reevaluate the patient's condition and institute appropriate corrective treatment.

Storage
Avoid storage at excessive heat. It is recommended that the product be stored at room temperature (25°C); brief exposure up to 40°C does not adversely affect the product.

Registration Number: 14 982 4549

Manufactured By
Teva Medical Ltd.,
P.O. Box 2, Ashdod 77100,
Israel
INFORMATION ON 10% DEXTROSE INJECTION WHEN USED AS INTRAVENOUS INJECTION

Contraindications
None known.

Warnings
10% Dextrose Injection is intended for intravenous administration only. It should not be administered subcutaneously or intramuscularly.

The administration of Intravenous Injections 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 injections may result in significant hypokalemia.

Administration by central venous catheter should be used only by those familiar with this technique and its complications.

Dextrose injection should not be administered simultaneously with blood through the same administration set because of the possibility of pseudoagglutination or hemolysis.

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.

Nausea, fever, and flushing of the skin have occurred.

If an adverse reaction does occur, the infusions should be discontinued, the patient evaluated, appropriate therapeutic countermeasures instituted, and the remainder of the fluid saved for examination if deemed necessary.

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.

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

Caution should be exercised in the administration of these injections to the very young and to elderly patients.

Administer so that extravasation does not occur. If thrombosis occurs during administration, stop injection and correct.

Solutions containing dextrose should be used with caution in patients with overt or subclinical diabetes mellitus, or carbohydrate intolerance.
Hyperglycemia and glycosuria may be functions of rate of administration or metabolic insufficiency. To minimize these conditions, slow the infusion rate, monitor blood and urine glucose; if necessary, administer insulin.

Vitamin B-complex deficiency may occur with dextrose administration.

**Dosage and Administration**

*Notes: Do not administer unless solution is clear and seal is intact.*

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Use of a final filter is recommended during administration of all parenteral solutions, where possible.

The dosage is usually dependent upon the age, weight and clinical condition of the patient, as well as laboratory determinations. All injections in plastic containers are intended for intravenous administration using sterile equipment. It is recommended that intravenous administration apparatus be replaced at least once every 24 hours.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. A pharmacist should be consulted, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, aseptic technique should be used. Thorough mixing should be performed when additives have been introduced.

*Solutions containing additives must not be stored.*

**Directions for Use of Plastic Bags**

*Warning:* Do not use plastic bags in series connections. Such use could result in air embolism due to residual air being drawn from the primary bag before administration of the fluid from the secondary bag is completed.

**To Open**

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

The overwrap is a moisture barrier. The inner bag maintains the sterility of the product.

Tear pouch down side at slit and remove solution container. 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 before preparing for administration.

**Preparation for Administration**

1. Suspend container from eyelet support.
2. Remove plastic protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

**To Add Medication Before Solution Administration**

*Warning:* Additives may be incompatible.

1. Prepare medication site.
2. Using syringe with 19-22 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 19-22 gauge needle, puncture resealable 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.
INFORMATION ON 10% DEXTROSE INJECTION WHEN USED AS PARENTERAL NUTRIENT

Contraindications
The infusion of hypertonic dextrose solutions is contraindicated in patients having intracranial or intraspinal hemorrhage, in patients who are severely dehydrated, in patients who are anuric, and in patients in hepatic coma.

Warnings
10% Dextrose Injection is intended for intravenous administration only. It should not be administered subcutaneously or intramuscularly.

Dilute before use to a concentration which will, when administered with an amino acid (nitrogen) source, result in an appropriate calorie to gram nitrogen ratio, and which has an osmolarity consistent with the route of administration.

Unless appropriately diluted, the infusion of hypertonic dextrose injections into a peripheral vein may result in vein irritation, vein damage, and thrombosis. Strongly hypertonic nutrient solutions should be administered through an indwelling intravenous catheter with the tip located in a large central vein such as the superior vena cava.

Dextrose injection should not be administered simultaneously with blood through the same infusion set because of the possibility of pseudoagglutination.

Adverse Reactions
Too rapid infusion of a hypertonic dextrose solution may result in diuresis, hyperglycemia, glycosuria, and hyperosmolar coma. Continual clinical monitoring of the patient is necessary in order to identify and initiate measures for these clinical conditions.

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, the infusion should be discontinued, the patient evaluated, appropriate therapeutic countermeasures instituted, and the remainder of the fluid saved for examination if deemed necessary.

Precautions
Administration of hypertonic dextrose (nutrient or solution) and amino acid solutions via central venous catheter may be associated with complications which can be prevented or minimized by careful attention to all aspects of the procedure. This includes attention to solution preparation, administration, and patient monitoring.

It is essential that a carefully prepared protocol, based upon current medical practice, be followed, preferably by an experienced team. The package insert of the protein (nitrogen) source should be consulted for dosage and all precautionary information.

During the prolonged parenteral therapy or whenever the condition of the patient warrants evaluation, clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid-base balance. Interruption or rapid cessation of hypertonic dextrose therapy may result in a hypoglycemic reaction. It is suggested that the patient be titrated with a dilute dextrose solution until the patient has reached glucose equilibrium.

Special care must be taken when giving hypertonic glucose to patients with overt or subclinical diabetes mellitus.

It has been suggested that glucose solutions should not be used after acute ischemic strokes as hyperglycemia has been implicated in increasing cerebral ischemic brain damage and in impairing recovery.
Care should be taken to avoid circulatory overload, particularly in patients with cardiac insufficiency. Caution must be exercised in the administration of these injections to patients receiving corticosteroids or corticotropin.

**Dosage and Administration**

*Notes: Do not administer unless solution is clear and seal is intact.*

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Use of a final filter is recommended during administration of all parenteral solutions, where possible.

Injection of the solution should be made slowly.

The maximum rate at which dextrose can be infused without producing glycosuria is 0.5 g/kg body weight/hour. About 95% of the dextrose is retained when infused at a rate of 0.8 g/kg/hour.

The dose of 10% Dextrose Injection is dependent upon the age, weight and clinical condition of the patient, as well as laboratory determinations.

When it is used as a caloric source in parenteral nutrition therapy, the package insert of the protein (nitrogen) source should be consulted for the correct carbohydrate dosage.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. A pharmacist should be consulted, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, aseptic technique should be used.

Thorough and careful mixing should be performed when additives have been introduced.

_Solutions containing additives must not be stored._

These admixed injections in plastic bags are intended for intravenous administration using sterile equipment.

Exposure of pharmaceutical products to heat should be minimized. Excessive heat should be avoided. It is recommended that products be stored at room temperature (25°C). Brief exposure up to 40°C does not adversely affect the product.

*Note: It is recommended that all intravenous administration apparatus, including the needle, be replaced at least once every 24 hours.*

**Directions for Use of Plastic Bags**

*Warning*: Do not use plastic bags in series connections. Such use could result in air embolism due to residual air being drawn from the primary bag before administration of the fluid from the secondary bag is completed.

**Preparation for Administration**

1. Suspend bag.
2. Remove plastic bag from outlet port at bottom of bag.
3. Attach administration set. Refer to complete directions accompanying set.

**To Add Medication**

Using syringe.

1. Prepare medication site.
2. Using a 20-22 gauge needle, puncture resealable rubber plug at target area and inject. Multiple additions may be made in this manner.
3. Mix solution and medication thoroughly. For high density medications such as potassium chloride, squeeze ports while ports are upright, and mix thoroughly.