20%, 50% Dextrose Injections
(Dextrose in Water) in Plastic Bags.

PARENTERAL NUTRIENTS

Description
20% and 50% Dextrose injections are sterile, nonpyrogenic and hypertonic solutions. They contain Dextrose in Water for Injection. The pH of the 50% Dextrose injection is adjusted with hydrochloric acid. Neither solution contains any antimicrobial agent or buffer. The composition, osmolarity, pH and calorie content are shown in Table 1 below:

<table>
<thead>
<tr>
<th>COMPOSITION</th>
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<tr>
<td><strong>Dextrose hydrous (g/L)</strong></td>
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<tr>
<td>20% Dextrose Injection</td>
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<tr>
<td>50% Dextrose Injection</td>
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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 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 standards for plastic containers as well as by tissue culture toxicity studies.

Clinical Pharmacology
Dextrose injections have value as a source of water and calories. They are capable of inducing diuresis depending on the clinical condition of the patient.

Indications
20% and 50% Dextrose Injections are indicated as a caloric component in a parenteral nutrition regimen. They are 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.
**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**

*Concentrated dextrose solutions should not be administered subcutaneously or intramuscularly.*

This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.

Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater that 4 to 5 µg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

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.

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

**Use in Pregnancy**

Animal reproduction studies have not been conducted with Dextrose Injections. It is also not known whether Dextrose Injections 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.

**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**

*Note: 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.*

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 20% and 50% 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.

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 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.

Registration Numbers:
20% Dextrose Injection: 043 96 23636 00.
50% Dextrose Injection: 043 97 23637 00.

Manufactured By
Teva Medical Ltd.,
P.O. Box 2, Ashdod 77100,
Israel