

Y36-002-531
Package Insert

EXCEL® CONTAINER

Dextrose Injections USP

DESCRIPTION

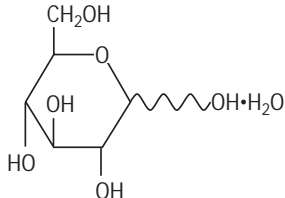
Rx only

Each 100 mL of 5% Dextrose Injection USP contains:
Hydrous Dextrose USP 5 g; Water for Injection USP qs
pH: 4.4 (3.5-6.5); Calculated Osmolarity: 250 mOsmol/liter
Calories per liter: 170

Each 100 mL of 10% Dextrose Injection USP contains:
Hydrous Dextrose USP 10 g; Water for Injection USP qs
pH: 4.4 (3.5-6.5); Calculated Osmolarity: 505 mOsmol/liter, hypertonic
Calories per liter: 340

Dextrose Injections USP are sterile, nonpyrogenic and contain no bacteriostatic or antimicrobial agents. These products are intended for intravenous administration.

The formula of the active ingredient is:

| Ingredient | Molecular Formula | Molecular Weight |
|----------------------|--|------------------|
| Hydrous Dextrose USP |  | 198.17 |

The EXCEL Container is Latex-free; PVC-free; and DEHP-free.

The plastic container is made from a multilayered film specifically developed for parenteral drugs. It contains no plasticizers and exhibits virtually no leachables. The solution contact layer is a rubberized copolymer of ethylene and propylene. The container is nontoxic and biologically inert. The container-solution unit is a closed system and is not dependent upon entry of external air during administration. The container is overwrapped to provide protection from the physical environment and to provide an additional moisture barrier when necessary.

Addition of medication should be accomplished using complete aseptic technique.

The closure system has two ports; the one for the administration set has a tamper evident plastic protector and the other is a medication addition site. Refer to the Directions for Use of the container.

CLINICAL PHARMACOLOGY

Dextrose Injections USP provide calories and are a source of water for hydration. They are capable of inducing diuresis depending on the clinical condition of the patient.

Dextrose is readily metabolized, may decrease losses of body protein and nitrogen, promotes glycogen deposition and decreases or prevents ketosis if sufficient doses are provided. 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).

INDICATIONS AND USAGE

These intravenous solutions are indicated for use in adults and pediatric patients as sources of calories and water for hydration.

CONTRAINDICATIONS

Solutions containing dextrose may be contraindicated in patients with hypersensitivity to corn products.

WARNINGS

The administration of intravenous solutions can cause fluid and/or solute overload resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentration.

WARNING: Dextrose Injection USP 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 than 4 to 5 $\mu\text{g}/\text{kg}/\text{day}$ accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

Prolonged infusion of isotonic or hypotonic dextrose in water may increase the volume of extracellular fluid and cause water intoxication.

Solutions containing dextrose without electrolytes should not be administered simultaneously with blood through the same infusion set because of the possibility of agglomeration.

Excessive administration of potassium-free dextrose solutions may result in significant hypokalemia. Serum potassium levels should be maintained and potassium supplemented as required.

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

PRECAUTIONS

General

These solutions should be used with care in patients with hypervolemia, renal insufficiency, urinary tract obstruction, or impending or frank cardiac decompensation.

Solutions containing dextrose should be used with caution in patients with overt or known subclinical diabetes mellitus or carbohydrate intolerance for any reason.

Essential electrolytes, minerals, and vitamins should be supplied as needed.

Hypokalemia may develop during parenteral administration of hypertonic dextrose solutions. Sufficient amounts of potassium should be added to dextrose solutions administered to fasting patients with good renal function, especially those on digitalis therapy.

To minimize the risk of possible incompatibilities arising from mixing this solution with other additives that may be prescribed, the final infusate should be inspected for cloudiness or precipitation immediately after mixing, prior to administration, and periodically during administration.

Do not use plastic container in series connection.

If administration is controlled by a pumping device, care must be taken to discontinue pumping action before the container runs dry or air embolism may result.

These solutions are intended for intravenous administration using sterile equipment. It is recommended that intravenous administration apparatus be replaced at least once every 24 hours.

Use only if solution is clear and container and seals are intact.

Dextrose Injection USP contains no more than 25 µg/L of aluminum.

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. Significant deviations from normal concentrations may require tailoring of the electrolyte pattern, in these or alternative solutions.

Drug Interactions

Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies with Dextrose Injections USP 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 Injections USP. It is also not known whether Dextrose Injections USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Dextrose Injections USP should be given to a pregnant woman only if clearly needed.

Labor and Delivery

As reported in the literature, dextrose solutions have been administered during labor and delivery. Caution should be exercised, and the fluid balance, glucose and electrolyte concentrations and acid-base balance, of both mother and fetus should be evaluated periodically or whenever warranted by the condition of the patient or fetus.

Nursing Mothers

Because many drugs are excreted in human milk, caution should be exercised when Dextrose Injections USP are administered to a nursing woman.

Pediatric Use

In neonates or in very small infants even small volumes of fluid may affect fluid and electrolyte balance. Care must be exercised in treatment of neonates, especially pre-term neonates, whose renal function may be immature and whose ability to excrete fluid and solute loads may be limited. Fluid intake, urine output, and serum electrolytes should be monitored closely.

Serum glucose concentrations should be frequently monitored when dextrose is prescribed to pediatric patients, particularly infants, neonates, and low birth weight infants.

See **WARNINGS** and **DOSAGE AND ADMINISTRATION**.

Geriatric Use

An evaluation of current literature revealed no clinical experience identifying differences in responses between the 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.

These drugs are known to be substantially excreted by the kidney, and the risk of toxic reactions to these drugs 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.

See **WARNINGS**.

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.

Too rapid infusion of hypertonic solutions may cause local pain and venous irritation. Rate of administration should be adjusted according to tolerance. Use of the largest peripheral vein and a small bore needle is recommended. (See **DOSAGE AND ADMINISTRATION**.)

The physician should also be alert to the possibility of adverse reactions to drug additives. Prescribing information for drug additives to be administered in this manner should be consulted.

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 a fluid or solute overload during parenteral therapy, reevaluate the patient's condition and institute appropriate corrective treatment.

DOSAGE AND ADMINISTRATION

These solutions are for intravenous use only.

Dosage is to be directed by a physician and is dependent upon age, weight, clinical condition of the patient and laboratory determinations. Frequent laboratory determinations and clinical evaluation are essential to monitor changes in blood glucose and electrolyte concentrations, and fluid and electrolyte balance during prolonged parenteral therapy.

When a hypertonic solution is to be administered peripherally, it should be slowly infused through a small bore needle, placed well within the lumen of a large vein to minimize venous irritation. Carefully avoid infiltration.

Fluid administration should be based on calculated maintenance or replacement fluid requirements for each patient.

Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

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

Pediatric Use

There is no specific pediatric dose. The dose is dependent on weight, clinical condition, and laboratory results. Follow recommendations of appropriate pediatric reference text. (See WARNINGS and PRECAUTIONS.)

HOW SUPPLIED

Dextrose Injections USP are supplied sterile and nonpyrogenic in EXCEL® Containers. The 1000 mL containers are packaged 12 per case, the 500 mL and 250 mL containers are packaged 24 per case.

| NDC | Cat. No. | Size |
|--|----------|---------|
| 5% Dextrose Injection USP (Canada DIN 01924281) | | |
| 0264-7510-00 | L5100 | 1000 mL |
| 0264-7510-10 | L5101 | 500 mL |
| 0264-7510-20 | L5102 | 250 mL |

10% Dextrose Injection USP

(Canada DIN 01924427)

| | | |
|--------------|-------|---------|
| 0264-7520-00 | L5200 | 1000 mL |
| 0264-7520-10 | L5201 | 500 mL |
| 0264-7520-20 | L5202 | 250 mL |

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. Protect from freezing. It is recommended that the product be stored at room temperature (25°C); however, brief exposure up to 40°C does not adversely affect the product.

Revised: February 2004

U.S. Patent No. 4,803,102

EXCEL is a registered trademark of B. Braun Medical Inc.

Made in USA

Directions for Use of EXCEL® Container

Caution: Do not use plastic container in series connection.

To Open

Tear overwrap down at notch and remove solution container. Check for minute leaks by squeezing solution container firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below before preparing for administration.

NOTE: Before use, perform the following checks:

Inspect each container. Read the label. Ensure solution is the one ordered and is within the expiration date.

INVERT CONTAINER AND CAREFULLY INSPECT THE SOLUTION IN GOOD LIGHT FOR CLOUDINESS, HAZE, OR PARTICULATE MATTER. ANY CONTAINER WHICH IS SUSPECT SHOULD NOT BE USED.

Use only if solution is clear and container and seals are intact.

Preparation for Administration

1. Remove plastic protector from sterile set port at bottom of container.
2. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Warning: Some additives may be incompatible.

To Add Medication Before Solution Administration

1. Prepare medication site.

2. Using syringe with 18-22 gauge needle, puncture medication port and inner diaphragm and inject.
3. Squeeze and tap ports while ports are upright and mix solution and medication thoroughly.

To Add Medication During Solution Administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 18-22 gauge needle of appropriate length (at least 5/8 inch), puncture resealable medication port and inner diaphragm and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by tapping and 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.

B BRAUN

B. BRAUN Medical Inc.

Irvine, CA USA 92614-5895

In Canada, distributed by:

B. Braun Medical Inc.

Scarborough, Ontario M1H 2W4