DEXTROSE- dextrose monohydrate injection, solution, concentrate
ICU Medical, Inc.

10% Dextrose Injection, USP
CONCENTRATED DEXTROSE IN WATER
Concentrated source of carbohydrate calories for intravenous infusion.
NOTE: This solution is hypertonic − see ***WARNINGS*** and ***PRECAUTIONS***.
Partial-Fill Flexible Plastic
Container Rx only

DESCRIPTION

10% Dextrose Injection, USP (concentrated dextrose in water) is a sterile, nonpyrogenic, hypertonic solution of Dextrose, USP in water for injection for intravenous administration after appropriate admixture or dilution.

10% Dextrose Injection, USP is provided as a 500 mL volume in a 1000 mL partial-fill container. The container is designed to facilitate admixture or dilution.

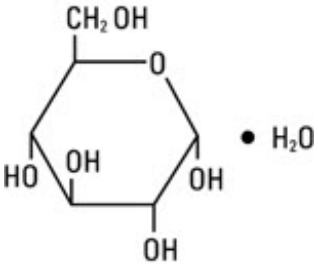
See table under ***HOW SUPPLIED*** for summary of content and characteristics of this concentrated solution.

The solution contains no bacteriostat, antimicrobial agent or added buffer and is intended only for use as a single-dose injection following admixture or dilution.

The flexible plastic container is fabricated from a specially formulated polyvinyl chloride. Water can permeate from inside the container into the overwrap but not in amounts sufficient to affect the solution significantly. Solutions in contact with the plastic container may leach out certain chemical components from the plastic in very small amounts; however, biological testing was supportive of the safety of the plastic container materials. 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.

Dextrose Injection, USP is a parenteral fluid and nutrient replenisher.

Dextrose Injection, 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:



Water for Injection, USP is chemically designated H_2O.

CLINICAL PHARMACOLOGY

When administered intravenously, 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 Injection, USP undergoes oxidation to carbon dioxide and water.

Water is an essential constituent of all body tissues and accounts for approximately 70% of total body weight. Average normal adult daily requirement ranges from two to three liters (1.0 to 1.5 liters each for insensible water loss by perspiration and urine production, respectively).

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

10% Dextrose Injection, USP (concentrated dextrose in water) in a partial-fill container is indicated for admixture with amino acids or dilution with other compatible IV fluids to provide a 5% final dextrose concentration for intravenous infusion in patients whose condition requires parenteral nutrition.

CONTRAINDICATIONS

A concentrated dextrose solution should not be used when intracranial or intraspinal hemorrhage is present nor in the presence of delirium tremens if the patient is already dehydrated.

Dextrose Injection, USP without electrolytes should not be administered simultaneously with blood through the same infusion set because of the possibility that pseudoagglutination of red cells may occur.

WARNINGS

Concentrated dextrose in water should be administered only after suitable dilution. Hypertonic dextrose solutions should be given slowly. Significant hyperglycemia and possible hyperosmolar syndrome may result from too rapid administration. The physician should be aware of the symptoms of hyperosmolar syndrome, such as mental confusion and loss of consciousness, especially in patients with chronic uremia and those with known carbohydrate intolerance.

The intravenous administration of this solution can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema.

WARNING: 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 than 4 to 5 mcg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

FOR PERIPHERAL VEIN ADMINISTRATION

Hypertonic dextrose solutions (above 5% concentration) should be given slowly, preferably through a small bore needle into a large vein, to minimize venous irritation.

FOR CENTRAL VENOUS ADMINISTRATION

Concentrated dextrose should be administered via central vein after appropriate admixture or dilution when required.

PRECAUTIONS

Electrolyte deficits, particularly in serum potassium and phosphate, may occur during prolonged use of concentrated dextrose solutions. Blood electrolyte monitoring is essential, and fluid and electrolyte imbalances should be corrected. Essential vitamins and minerals also should be provided as needed.

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

Care should be exercised to insure that the needle (or catheter) is well within the lumen of the vein and that extravasation does not occur.

Concentrated dextrose solutions should not be administered subcutaneously or intramuscularly.

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

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

This product contains no more than 25 mcg/L of aluminum.

ADVERSE REACTIONS

Hyperosmolar syndrome, resulting from excessively rapid administration of concentrated dextrose may cause hypovolemia, dehydration, mental confusion and/or loss of consciousness.

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 during therapy, re-evaluate the patient and institute appropriate corrective measures. (See ***WARNINGS*** and ***PRECAUTIONS***).

DOSAGE AND ADMINISTRATION

Concentrated Dextrose in Water is administered by slow intravenous infusion (a) after admixture with amino acid solutions or (b) after dilution with other compatible IV fluids. Dosage should be adjusted to meet the requirements of each individual patient.

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

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.

A list of nutritional admixture values is appended.

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

Drug Interaction

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

Some opacity of the plastic due to moisture absorption during sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually.

WARNING: Do not use flexible container in series connections.

HOW SUPPLIED

10% Dextrose Injection, USP is supplied in single-dose, partial-fill, flexible containers as follows: a 500 mL volume in a 1000 mL container. See the following table.

Concentrated Dextrose In Water Content and Characteristics

NDC No.	% Conc.	Fill Volume (mL)	Total Grams of Dextrose Hydrous Per Container	kcal* /100 mL (Per Container)	mOsmol/liter (calc.)	pH (range)
0409-7938-19	10	500	50	34 (170)	505	4.3 (3.2 to 6.5)

0990-7938-19	10	500	50	34 (170)	505	4.3 (3.2 to 6.5)

* Caloric value calculated on the basis of 3.4 kcal/g of dextrose, hydrous.

ICU Medical is transitioning NDC codes from the "0409" to a "0990" labeler code. Both NDC codes are expected to be in the market for a period of time.

Nutritional Admixture Values Equal volumes of 10% Dextrose Injection, USP and Aminosyn™ 7% provide the following:

Dextrose Pre-Dilution Concentration	Admixture Non-Protein kcal/g N	Admixture Non-Protein kcal/liter	Admixture g N/liter	Admixture Dextrose Concentration
10%	31	170	5.5	5%

Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.] Protect from freezing.

Revised: November, 2018

EN-4694

ICU Medical, Inc., Lake Forest, Illinois, 60045, USA

PRINCIPAL DISPLAY PANEL - 500 mL Bag Label

500 mL
NDC 0990-7938-19
IN 1000 mL PARTIAL-FILL CONTAINER
10% DEXTROSE
Injection, USP

EACH 100 mL CONTAINS DEXTROSE, HYDROUS 10 g IN WATER FOR INJECTION.
505 mOsmol/LITER (CALC.)
pH 4.3 (3.2 TO 6.5)

CAUTION: HYPERTONIC. ADMINISTER ONLY AFTER DILUTION. DEXTROSE SOLUTIONS WITHOUT SALTS SHOULD NOT BE USED IN BLOOD TRANSFUSIONS BECAUSE OF POSSIBLE ROULEAU FORMATION.

ADDITIVES MAY BE INCOMPATIBLE. CONSULT WITH PHARMACIST, IF AVAILABLE. WHEN INTRODUCING ADDITIVES, USE ASEPTIC TECHNIQUE, MIX THOROUGHLY AND DO NOT STORE.

SINGLE-DOSE CONTAINER. FOR I.V. USE. USUAL DOSAGE: SEE INSERT. STERILE, NONPYROGENIC. USE ONLY IF SOLUTION IS CLEAR AND CONTAINER IS UNDAMAGED. MUST NOT BE USED IN SERIES CONNECTIONS.

Rx ONLY
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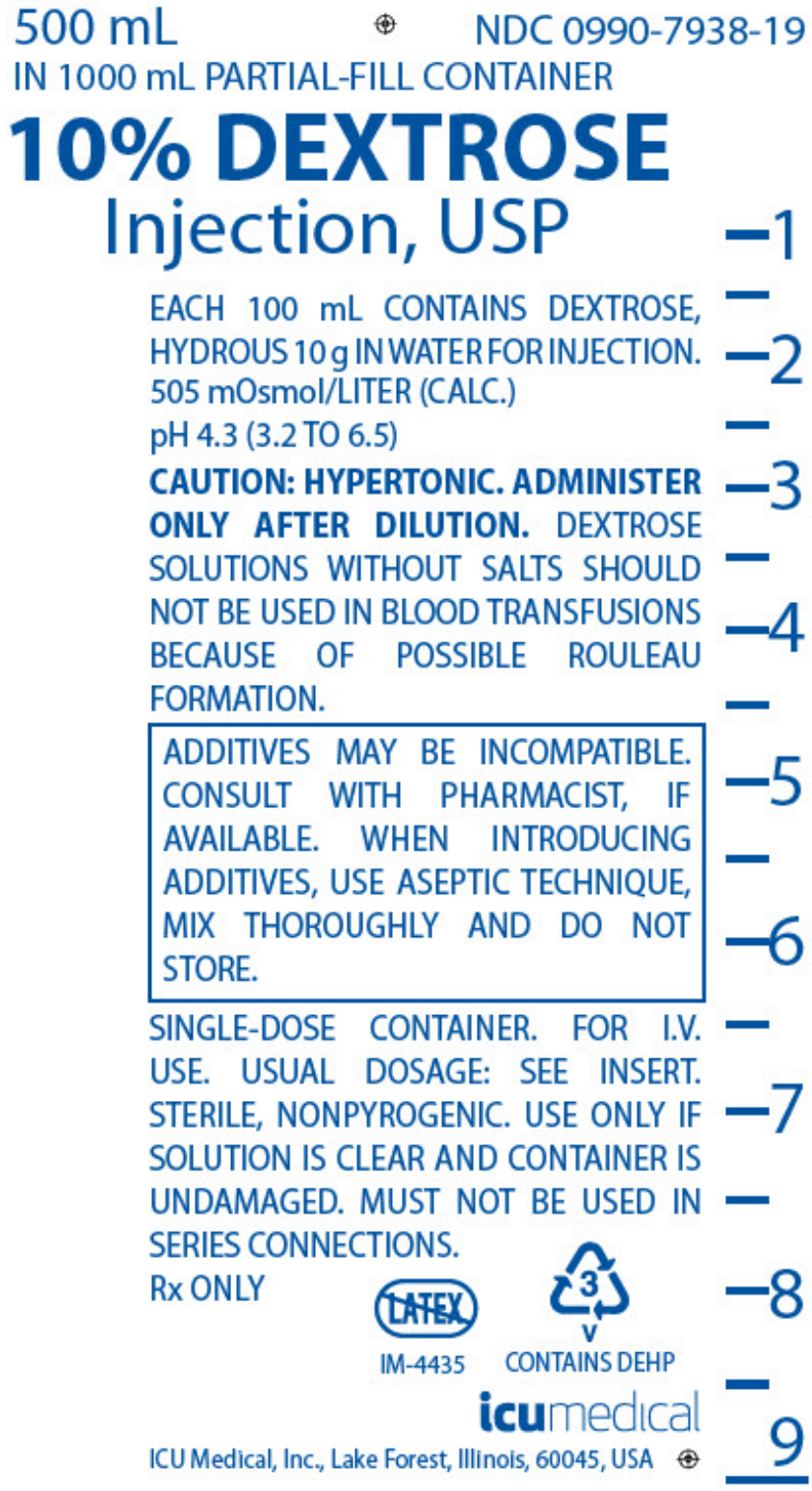

PRINCIPAL DISPLAY PANEL - 500 mL Bag Pouch Label

TO OPEN — TEAR AT NOTCH

The overwrap is a moisture and oxygen barrier. Do not remove unit from overwrap until ready for use. Visually inspect overwrap for tears or holes. Discard unit if overwrap is damaged. Use unit promptly when pouch is opened.
Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room

Temperature.] Protect from freezing. See insert. After removing the overwrap, check for minute leaks by squeezing container firmly. If leaks are found, discard solution as sterility may be impaired.

Rx only

WR-0559

ICU Medical, Inc., Lake Forest, Illinois, 60045 USA

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℞ only

DEXTROSE

dextrose monohydrate injection, solution, concentrate

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0990-7938
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	10 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0990-7938-19	12 in 1 CASE	11/20/2019	
1		1 in 1 POUCH		
1		500 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018080	11/20/2019	

Labeler - ICU Medical, Inc. (118380146)

Registrant - Hospira, Inc. (093132819)

Revised: 11/2025 ICU Medical, Inc.