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

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use 10% DEXTROSE INJECTION safely and effectively. See full prescribing information for 10% DEXTROSE INJECTION.

10% DEXTROSE INJECTION, for intravenous use
Initial U.S. Approval: 1940

RECENT MAJOR CHANGES

Contraindications (4)	11/2023
Warnings and Precautions (5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7)	11/2023

INDICATIONS AND USAGE

10% Dextrose Injection 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. (1)

DOSAGE AND ADMINISTRATION

- See full prescribing information on preparation, administration, and dosing information. (2.1, 2.2)
- Discontinue infusion if an adverse reaction occurs (2.3)

DOSAGE FORMS AND STRENGTHS

Injection:

- 10% (0.1 grams/mL): 10 grams of dextrose hydrous per 100 mL in partial-fill flexible containers: 500 mL. (3)

CONTRAINDICATIONS

- Clinically significant hyperglycemia. (4)
- Known hypersensitivity to dextrose. (4)

WARNINGS AND PRECAUTIONS

- Hyperglycemia or Hyperosmolar Hyperglycemic State: Monitor blood glucose and administer insulin as needed. (5.1)
- Hypersensitivity Reactions: Monitor for signs and symptoms and discontinue infusion if reactions occur. (5.2)
- Vein Damage and Thrombosis: Consider central vein when administering more than 5% dextrose or with an osmolarity of at least 900 mOsm/L or when there is peripheral vein irritation, phlebitis, and/or associated pain. (2.2, 5.3)
- Hyponatremia: Avoid in patients with or at risk for hyponatremia. If use cannot be avoided, monitor serum sodium concentrations. (5.4)
- Electrolyte Imbalance and Fluid Overload: Avoid in patients with or at risk for fluid and/or solute overloading. If use cannot be avoided, monitor daily fluid balance, electrolyte concentrations, and acid-base balance, as needed and especially during prolonged use. (5.5)
- Aluminum Toxicity: Dextrose Injection contains aluminum that may be toxic. Patients with impaired renal function, and preterm infants, at higher risk. Limit aluminum to less than 4 mcg/kg/day (5.6)
- Refeeding Syndrome: Monitor severely undernourished patients and slowly increase nutrient intake. (5.7)

ADVERSE REACTIONS

The most common adverse reactions are hyperglycemia, hypersensitivity reactions, hyponatremia, infection both systemic and at the injection site, vein thrombosis or phlebitis, and electrolyte imbalance. (6)

To report SUSPECTED ADVERSE REACTIONS, contact ICU Medical, Inc. at 1-800-441-4100 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Additives may be incompatible. When introducing additives, use aseptic technique, mix thoroughly and do not store. (7)
- Other Products that Affect Glycemic Control, Vasopressin or Fluid and/or Electrolyte Balance: Monitor blood glucose concentrations, fluid balance, serum electrolyte concentrations and acid-base balance. (7.1)

USE IN SPECIFIC POPULATIONS

Pediatric Use: Increased risk of hypoglycemia/hyperglycemia; monitor serum glucose concentrations. (8.4)
See 17 for PATIENT COUNSELING INFORMATION.

Revised: 11/2023

FULL PRESCRIBING INFORMATION: CONTENTS*

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* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

10% Dextrose Injection 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.

2 DOSAGE AND ADMINISTRATION

2.1 Important Administration Instructions

- 10% Dextrose 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.
- 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.
- Peripheral administration of 5% dextrose is generally acceptable, however, consider central vein when administering more than 5% dextrose or with an osmolarity of at least 900 mOsm/L or when there is peripheral vein irritation, phlebitis, and/or associated pain *[see Warnings and Precautions (5.3)]*.
- For central venous administration, concentrated dextrose should be administered after appropriate admixture or dilution when required.
- Do not administer Dextrose Injection simultaneously with blood products through the same administration set because of the possibility of pseudoagglutination or hemolysis.
- To prevent air embolism, use a non-vented infusion set or close the vent on a vented set, avoid multiple connections, do not connect flexible containers in series, fully evacuate residual gas in the container prior to administration, do not pressurize the flexible container to increase flow rates, and if administration is controlled by a pumping device, turn off pump before the container runs dry.
- 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 included below.

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%

- Parenteral drug products should be inspected visually for particulate matter and

discoloration prior to administration, whenever solution and container permit.
- The solution should be clear and there should be no precipitates.
- 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 container is undamaged. Discard unused portion.
- 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.
- Use of a final filter is recommended during administration of parenteral solutions, where possible.

2.2 Dosing Information

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.

The choice of dextrose concentration, rate and volume depends on the age, weight, clinical and metabolic conditions of the patient and concomitant therapy. Electrolyte supplementation may be indicated according to the clinical needs of the patient.

The administration rate should be governed, especially for premature infants with low birth weight, during the first few days of therapy, by the patient's tolerance to dextrose.

Increase the infusion rate gradually as indicated by frequent monitoring of blood glucose concentrations *[see Warnings and Precautions (5.1), Use in Specific Populations (8.4)]*.

2.3 Discontinuation of Dextrose Injection

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.

3 DOSAGE FORMS AND STRENGTHS

10% Dextrose Injection, USP is a clear, sterile, nonpyrogenic solution of dextrose supplied in single-dose, partial-fill, flexible containers:
- 10% (0.1 grams/mL): 10 grams of dextrose hydrous per 100 mL provided as a 500 mL volume in a 1000 mL partial-fill container.

4 CONTRAINDICATIONS

The use of 10% Dextrose Injection is contraindicated in patients with:
- Clinically significant hyperglycemia *[see Warnings and Precautions (5.1)]*.
- Known hypersensitivity to dextrose *[see Warnings and Precautions (5.2)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Hyperglycemia and Hyperosmolar Hyperglycemic State

The use of dextrose infusions in patients with impaired glucose tolerance may worsen hyperglycemia. Administration of dextrose at a rate exceeding the patient's utilization rate may lead to hyperglycemia, coma, and death.

Hyperglycemia is associated with an increase in serum osmolality, resulting in osmotic diuresis, dehydration and electrolyte losses *[see Warnings and Precautions (5.5)]*. Patients with underlying CNS disease and renal impairment who receive dextrose infusions, may be at greater risk of developing hyperosmolar hyperglycemic state.

Monitor blood glucose levels and treat hyperglycemia to maintain levels within normal limits while administering Dextrose Injection. Insulin may be administered or adjusted to maintain optimal blood glucose levels during 10% Dextrose Injection administration.

5.2 Hypersensitivity Reactions

Hypersensitivity and infusion reactions, including anaphylaxis, have been reported with Dextrose Injection *[see Adverse Reactions (6)]*. Stop infusion immediately and treat patient accordingly if signs or symptoms of a hypersensitivity reaction develop. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

5.3 Vein Damage and Thrombosis

Peripheral administration of 5% Dextrose Injection is generally acceptable, however, consider central vein when administering more than 5% dextrose or with an osmolarity of ≥ at least 900 mOsm/L or when there is peripheral vein irritation, phlebitis, and/or associated pain. The infusion of hypertonic solutions into a peripheral vein may result in vein irritation, vein damage, and/or thrombosis. The primary complication of peripheral access is venous thrombophlebitis, which manifests as pain, erythema, tenderness or a palpable cord. Remove the catheter as soon as possible, if thrombophlebitis develops.

5.4 Hyponatremia

10% Dextrose Injection is a hypertonic solution *[see Description (11)]*. In the body, however, glucose containing fluids can become extremely physiologically hypotonic due to rapid glucose metabolization. Monitoring of serum sodium is particularly important for hypotonic fluids.

Depending on the tonicity of the solution, the volume and rate of infusion, and depending on a patient's underlying clinical condition and capability to metabolize glucose, intravenous administration of glucose can cause electrolyte disturbances, most importantly hypo-or hyperosmotic hyponatremia. Monitor serum sodium to minimize the risk of hyponatremia.

The risk for hyponatremia is increased in pediatric patients, elderly patients, postoperative patients, those with psychogenic polydipsia, and in patients treated with medications that increase the risk of hyponatremia (such as diuretics, certain antiepileptic and psychotropic medications). Close clinical monitoring may be warranted.

Acute hyponatremia can lead to acute hyponatremic encephalopathy characterized by headache, nausea, seizures, lethargy and vomiting. Patients with brain edema are at particular risk of severe, irreversible and life-threatening brain injury. Patients at increased risk for developing complications of hyponatremia, such as hyponatremic

encephalopathy include pediatric patients; women, in particular, premenopausal women; patients with hypoxemia; and in patients with underlying central nervous system disease *[see Use in Specific Populations (8.4, 8.5)]*.

Avoid Dextrose Injection in patients with or at risk for hyponatremia. If use cannot be avoided, monitor serum sodium concentrations.

Rapid correction of hyponatremia is potentially dangerous with risk of serious neurologic complications. Brain adaptations reducing risk of cerebral edema make the brain vulnerable to injury when chronic hyponatremia is too rapidly corrected, which is known as osmotic demyelination syndrome (ODS). To avoid complications, monitor serum sodium and chloride concentrations, fluid status, acid-base balance, and signs of neurologic complications.

High volume infusion must be used with close monitoring in patients with cardiac or pulmonary failure, and in patients with non-osmotic vasopressin release (including SIADH), due to the risk of hospital-acquired hyponatremia.

5.5 Electrolyte Imbalance and Fluid Overload

Electrolyte deficits, particularly in serum potassium and phosphate, may occur during prolonged use of concentrated dextrose solutions.

Depending on the volume and rate of infusion, the patient's underlying clinical condition and capability to metabolize dextrose, intravenous administration of Dextrose Injection can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, (including hypoosmotic hyponatremia), overhydration, congested states or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations in the administered solution. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations in the solution.

Avoid Dextrose Injection in patients with or at risk for fluid and/or solute overloading. If use cannot be avoided, monitor fluid balance, blood electrolyte levels, concentration of glucose, acid-base balance, correct fluid and electrolyte imbalances during prolonged parenteral therapy or whenever the condition of the patient or the rate of administration warrants such evaluation and acid-base balance as needed and especially during prolonged use. Additional monitoring is recommended for patients with water and electrolyte disturbances that could be aggravated by increased glucose, insulin administration and/or free water load. Patients at increased risk for developing hyponatremic encephalopathy include pediatric patients; elderly patients, women, in particular premenopausal women; patients with hypoxemia; and patients with underlying CNS disease *[see Use in Specific Populations (8.4, 8.5)].*

5.6 Aluminum Toxicity

10% Dextrose Injection contains no more than 25 mcg/L of aluminum. However, with prolonged parenteral administration in patients with renal impairment, the aluminum contained in Dextrose Injection may reach toxic levels. Preterm infants are at greater risk because their kidneys are immature, and they require large amounts of concomitant calcium and phosphate solutions that contain aluminum. Patients with renal impairment, including preterm infants, 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 of total parenteral nutrition products.

5.7 Refeeding Syndrome

Refeeding severely undernourished patients may result in refeeding syndrome, characterized by the intracellular shift of potassium, phosphorus, and magnesium as the patient becomes anabolic. Thiamine deficiency and fluid retention may also develop. To prevent these complications, monitor severely undernourished patients and slowly increase nutrient intake.

6 ADVERSE REACTIONS

The following adverse reactions associated with the use of 10% Dextrose Injection were identified in clinical studies or postmarketing reports. Because some of these reactions were reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Hyperglycemia and hyperosmolar hyperglycemic state *[see Warnings and Precautions (5.1)]*
- *Hypersensitivity Reactions*: anaphylaxis, pruritis, bronchospasm, cyanosis, angioedema, hypotension, pyrexia, chills, and rash *[see Warnings and Precautions (5.2)]*
- *Infusion Site Reactions*: infusion site phlebitis, infusion site erythema, vein damage and thrombosis, and infusion site thrombophlebitis *[see Warnings and Precautions (5.3)]*
- Hyponatremia and hyponatremic encephalopathy *[see Warnings and Precautions (5.4)]*
- Electrolyte imbalance and fluid overload *[see Warnings and Precautions (5.5)]*
- Aluminum toxicity *[see Warnings and Precautions (5.6)]*
- Refeeding syndrome *[see Warnings and Precautions (5.7)]*
- Pulmonary vascular precipitates

7 DRUG INTERACTIONS

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

7.1 Other Products that Affect Glycemic Control, Vasopressin or Fluid and/or Electrolyte Balance

Dextrose Injection can affect glycemic control, vasopressin and fluid and/or electrolyte balance *[see Warnings and Precautions (5.1, 5.4, 5.5)]*. Monitor blood glucose concentrations, fluid balance, serum electrolyte concentrations and acid-base balance when using Dextrose Injection in patients treated with other substances that affect glycemic control, vasopressin or fluid and/or electrolyte balance.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Appropriate administration of Dextrose Injection during pregnancy is not expected to cause adverse developmental outcomes, including congenital malformations. Animal reproduction studies have not been conducted with injectable dextrose solutions.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively

8.2 Lactation

Risk Summary

There are no data on the presence of dextrose in human milk, the effects on a breastfed infant, or the effects on milk production. The lack of clinical data during lactation precludes a clear determination of the risk of Dextrose Injection to an infant during lactation; therefore, the developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Dextrose Injection and any potential adverse effects on the breastfed infant from Dextrose Injection or from the underlying maternal condition.

8.4 Pediatric Use

The safety profile of Dextrose Injection in pediatric patients is similar to adults.

Neonates, especially premature infants with low birth weight, are at increased risk of developing hypo-or hyperglycemia and therefore need close monitoring during treatment with intravenous glucose infusions to ensure adequate glycemic control in order to avoid potential long-term adverse effects.

Closely monitor plasma electrolyte concentrations in pediatric patients who may have impaired ability to regulate fluids and electrolytes. In very low birth weight infants, excessive or rapid administration of Dextrose Injection may result in increased serum osmolality and risk of intracerebral hemorrhage.

Children (including neonates and older children) are at increased risk of developing hyponatremia as well as for developing hyponatremic encephalopathy *[see Warnings and Precautions (5.4)].*

Because of immature renal function, preterm infants receiving prolonged treatment with Dextrose Injection, may be at risk aluminum toxicity *[see Warnings and Precautions (5.6)]*.

8.5 Geriatric Use

Clinical studies of Dextrose Injection did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Elderly patients are at increased risk of developing hyponatremia as well as for

developing hyponatremic encephalopathy *[see Warnings and Precautions (5.4)]*. Other reported clinical experience has not identified 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.

Dextrose 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.

10 OVERDOSAGE

An increased infusion rate of Dextrose Injection or administration of dextrose solutions can cause hyperglycemia, hyperosmolality, and adverse effects on water and electrolyte balance *[see Warnings and Precautions (5.1, 5.5)].*

Severe hyperglycemia and severe dilutional hyponatremia, and their complications, can be fatal. Discontinue infusion, reduce dose and institute appropriate corrective measures such as administration of exogenous insulin.

Discontinue infusion and institute appropriate corrective measures in the event of overhydration or solute overload during therapy, with particular attention to CNS, respiratory and cardiovascular systems.

If over-exposure occurs, contact the Poison Control Center at 1-800-222-1222 for current information on the management of poisoning or overdosage.

11 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.

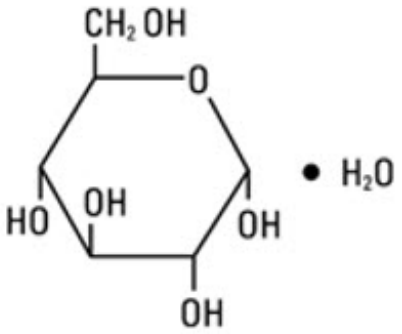
See table under *How Supplied/Storage and Handling (16)* for summary of content and characteristics of this concentrated solution.

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 ($C_6H_{12}O_6$ • H_2O), a hexose sugar freely soluble in water. It has the following structural formula:



Water for Injection, USP is chemically designated H_2O.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

When administered intravenously, solutions containing carbohydrate in the form of dextrose restore blood glucose levels and provide calories.

12.2 Pharmacodynamics

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.

16 HOW SUPPLIED/STORAGE AND HANDLING

10% Dextrose Injection, USP is supplied in single-dose, 500 mL volume in a 1000 mL partial-fill flexible 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-	10	500	50	34 (170)	505	4.3 (3.2 to

7938-19	10	500	50	34 (170)	505	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.

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

17 PATIENT COUNSELING INFORMATION

Inform patients, caregivers, or home healthcare providers of the following risks of 10% Dextrose Injection:

- Hyperglycemia and hyperosmolar hyperglycemic state *[see Warnings and Precautions (5.1)]*
- Hypersensitivity reactions *[see Warnings and Precautions (5.2)]*
- Vein damage and thrombosis *[see Warnings and Precautions (5.3)]*
- Hyponatremia *[see Warnings and Precautions (5.4)]*
- Electrolyte imbalance and fluid overload *[see Warnings and Precautions (5.5)]*
- Aluminum toxicity *[see Warnings and Precautions (5.6)]*
- Refeeding syndrome *[see Warnings and Precautions (5.7)]*

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

IFU0000543

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

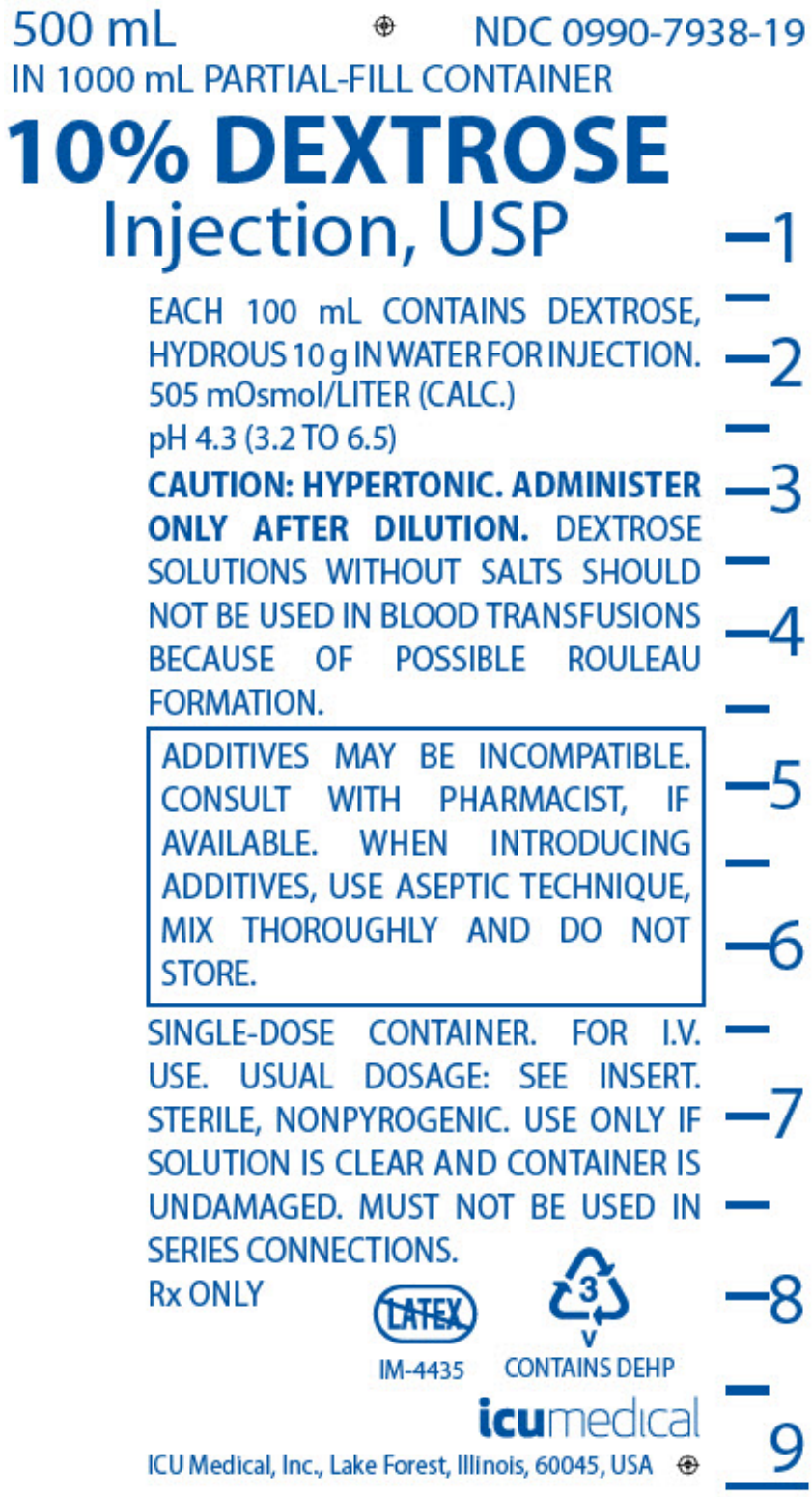
PHARMACIST, IF AVAILABLE.
WHEN INTRODUCING ADDITIVES, USE ASEPTIC TECHNIQUE, MIX THOROUGHLY AND DO NOT STORE.

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
IM-4435
3
V
CONTAINS DEHP

icumedical

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



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

icumedical

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.

℞ 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)

Revised: 11/2019 ICU Medical Inc.