

DEXTROSE- dextrose monohydrate injection, solution
ICU Medical Inc.

Dextrose Injection, USP
Flexible Plastic
Container
only

Rx

DESCRIPTION

Dextrose Injection, USP solutions are sterile and nonpyrogenic. They are parenteral solutions containing various concentrations of dextrose in water for injection intended for intravenous administration.

Each 100 mL of 5% Dextrose Injection, USP, contains dextrose, hydrous 5 g in water for injection. The caloric value is 170 kcal/L. The osmolarity is 252 mOsmol/L (calc.), which is slightly hypotonic.

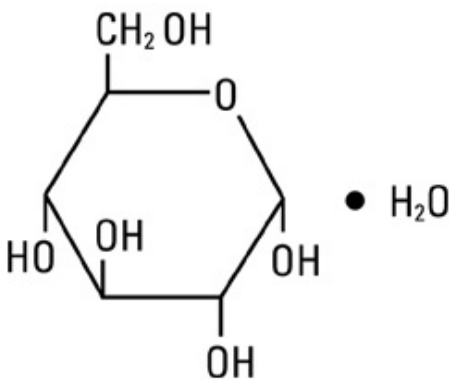
Each 100 mL of 10% Dextrose Injection, USP, contains dextrose, hydrous 10 g in water for injection. The caloric value is 340 kcal/L. The osmolarity is 505 mOsmol/L (calc.), which is hypertonic.

The pH for both concentrations is 4.3 (3.2 to 6.5).

The solutions contain no bacteriostat, antimicrobial agent or added buffer and each is intended only as a single-dose injection. When smaller doses are required the unused portion should be discarded.

The solutions are parenteral fluid and nutrient replenishers.

Dextrose, 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 H₂O.

The flexible plastic container is fabricated from a specially formulated polyvinylchloride. 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.

CLINICAL PHARMACOLOGY

When administered intravenously, these solutions provide a source of water and carbohydrate.

Isotonic and hypertonic concentrations of dextrose are suitable for parenteral maintenance of water requirements when salt is not needed or should be avoided.

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 injected parenterally 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 requirements range from two to three liters (1.0 to 1.5 liters each for insensible water loss by perspiration and urine production).

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

Intravenous solutions containing dextrose are indicated for parenteral replenishment of fluid and minimal carbohydrate calories as required by the clinical condition of the patient.

CONTRAINDICATIONS

Dextrose Injection 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

Excessive administration of potassium-free solutions may result in significant hypokalemia.

The intravenous administration of these solutions 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 administered parenteral solutions. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of such solutions.

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.

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

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

Carcinogenesis, Mutagenesis, Impairment of Fertility: Studies with Dextrose Injection, 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. 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.

Nursing Mothers: Caution should be exercised when Dextrose Injection, USP is administered to a nursing mother.

Pediatric Use: The safety and effectiveness in the pediatric population are based on the similarity of the clinical conditions of the pediatric and adult populations. In neonates or very small infants the volume of fluid may affect fluid and electrolyte balance.

Frequent monitoring of serum glucose concentrations is required when dextrose is prescribed to pediatric patients, particularly neonates and low birth weight infants.

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

Geriatric Use: An evaluation of current literature revealed no clinical experience identifying differences in response between 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.

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.

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

DOSAGE AND ADMINISTRATION

The dose is dependent upon the age, weight and clinical condition of the patient.

As reported in the literature, the dosage and constant infusion rate of intravenous dextrose must be selected with caution in pediatric patients, particularly neonates and low birth weight infants, because of the increased risk of hyperglycemia/hypoglycemia.

Drug Interactions

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

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

INSTRUCTIONS FOR USE

To Open:

Tear outer wrap at notch and remove solution container. If supplemental medication is desired, follow directions below before preparing for administration.

To Add Medication

1. Prepare additive port.
2. Using aseptic technique and an additive delivery needle of appropriate length, puncture resealable additive port at target area, inner diaphragm and inject. Withdraw needle after injecting medication.
3. The additive port may be protected by covering with an additive cap.
4. Mix container contents thoroughly.

Preparation for Administration

(Use aseptic technique)

1. Close flow control clamp of administration set.
2. Remove cover from outlet port at bottom of container.
3. Insert piercing pin of administration set into port with a twisting motion until the set is firmly seated. **NOTE:** When using a vented administration set, replace bacterial retentive air filter with piercing pin cover. Insert piercing pin with twisting motion until shoulder of air filter housing rests against the outlet port flange.
4. Suspend container from hanger.
5. Squeeze and release drip chamber to establish proper fluid level in chamber.
6. Attach venipuncture device to set.
7. Open clamp to expel air from set and venipuncture device. Close clamp.
8. Perform venipuncture.
9. Regulate rate of administration with flow control clamp.

WARNING: Do not use flexible container in series connections.

HOW SUPPLIED

Dextrose Injection, USP is supplied in single-dose flexible plastic containers in various sizes and concentrations as shown in the accompanying Table.

NDC No.	Product	Container size (mL)
0409-7922-61*	5% Dextrose Injection, USP	150
0990-7922-61*	5% Dextrose Injection, USP	150
0409-7922-53†	5% Dextrose Injection, USP	250
0990-7922-53†	5% Dextrose Injection, USP	250
0409-7922-02*	5% Dextrose Injection, USP	250
0990-7922-02*	5% Dextrose Injection, USP	250
0409-7922-03†	5% Dextrose Injection, USP	500

0990-7922-03 ^{*,†}	5% Dextrose Injection, USP	500
0409-7922-55 [*]	5% Dextrose Injection, USP	500
0990-7922-55 ^{*,†}	5% Dextrose Injection, USP	500
0409-7922-09 ^{*,†}	5% Dextrose Injection, USP	1000
0990-7922-09 ^{*,†}	5% Dextrose Injection, USP	1000
0409-7923-20 [*]	5% Dextrose Injection, USP	25
0990-7923-20 [*]	5% Dextrose Injection, USP	25
0409-7923-36 [*]	5% Dextrose Injection, USP	50
0990-7923-36 [*]	5% Dextrose Injection, USP	50
0409-7923-13 [*]	5% Dextrose Injection, USP	50
0990-7923-13 [*]	5% Dextrose Injection, USP	50
0409-7923-23 [*]	5% Dextrose Injection, USP	100
0990-7923-23 [*]	5% Dextrose Injection, USP	100
0409-7923-37 [*]	5% Dextrose Injection, USP	100
0990-7923-37 [*]	5% Dextrose Injection, USP	100
0409-7930-02 [*]	10% Dextrose Injection, USP	250
0990-7930-02 [*]	10% Dextrose Injection, USP	250
0409-7930-03 [†]	10% Dextrose Injection, USP	500
0990-7930-03 ^{*,†}	10% Dextrose Injection, USP	500
0409-7930-09 [†]	10% Dextrose Injection, USP	1000
0990-7930-09 ^{*,†}	10% Dextrose Injection, USP	1000

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

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

† Manufactured for ICU Medical, Inc., Lake Forest, Illinois, 60045, USA

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

Revised: December, 2020

IFU0000281

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PRINCIPAL DISPLAY PANEL - 100 mL Bag Label

100 mL

NDC 0990-7923-37

5% Dextrose
Injection, USP

EACH 100 mL CONTAINS DEXTROSE,
HYDROUS 5 g.
252 mOsmol/LITER (CALC). pH 4.3 (3.2 to 6.5).
DEXTROSE SOLUTIONS WITHOUT
SALTS SHOULD NOT BE USED IN BLOOD
TRANSFUSIONS BECAUSE OF POSSIBLE
ROULEAU FORMATION. ADDITIVES MAY BE
INCOMPATIBLE. 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


ICU Medical, Inc.,
Lake Forest, Illinois, 60045, USA
IM-4313

3

V




CONTAINS DEHP

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100 mL  NDC 0990-7923-37

5% Dextrose Injection, USP

EACH 100 mL CONTAINS DEXTROSE,
HYDROUS 5 g.
252 mOsmol/LITER (CALC). pH 4.3 (3.2 to 6.5).
DEXTROSE SOLUTIONS WITHOUT
SALTS SHOULD NOT BE USED IN BLOOD
TRANSFUSIONS BECAUSE OF POSSIBLE
ROULEAU FORMATION. ADDITIVES MAY BE
INCOMPATIBLE. 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  
ICU Medical, Inc.,
Lake Forest, Illinois, 60045, USA
IM-4313  CONTAINS DEHP
icumedical

PRINCIPAL DISPLAY PANEL - 250 mL Bag Label

250 mL
NDC 0990-7922-53

5% DEXTROSE
Injection, USP

EACH 100 mL CONTAINS DEXTROSE,
HYDROUS 5 g IN WATER FOR
INJECTION.
252 mOsmol/LITER (CALC.)
pH 4.3 (3.2 to 6.5)
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

3

V

CONTAINS DEHP

IM-4428

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

icumedical

250 mL

NDC 0990-7922-53

5% DEXTROSE Injection, USP

EACH 100 mL CONTAINS DEXTROSE,
HYDROUS 5 g IN WATER FOR
INJECTION.

252 mOsmol/LITER (CALC.)

pH 4.3 (3.2 to 6.5)

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.

50

100

150

200

Rx ONLY



CONTAINS DEHP



IM-4428

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



PRINCIPAL DISPLAY PANEL - 500 mL Bag Label

500 mL

NDC 0990-7930-03

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)

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 INTRAVENOUS OR SUBCUTANEOUS 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

3
V
CONTAINS DEHP

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ICU Medical, Inc., Lake Forest, Illinois, 60045, USA
IM-4454

500 mL

NDC 0990-7930-03

⊕

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)

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 INTRAVENOUS OR SUBCUTANEOUS 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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CONTAINS DEHP

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



IM-4454

DEXTROSE

dextrose monohydrate injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0990-7923
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R00K)	DEXTROSE MONOHYDRATE	5 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:0990-7923-20	12 in 1 CASE	08/01/2019	
1		4 in 1 POUCH		
1		25 mL in 1 BAG; Type 0: Not a Combination Product		
2	NDC:0990-7923-23	48 in 1 CASE	08/01/2019	
2		1 in 1 POUCH		
2		100 mL in 1 BAG; Type 0: Not a Combination Product		
3	NDC:0990-7923-36	20 in 1 CASE	07/15/2019	
3		4 in 1 POUCH		
3		50 mL in 1 BAG; Type 0: Not a Combination Product		
4	NDC:0990-7923-37	20 in 1 CASE	07/15/2019	
4		4 in 1 POUCH		
4		100 mL in 1 BAG; Type 0: Not a Combination Product		
5	NDC:0990-7923-13	48 in 1 CASE	08/01/2019	
5		1 in 1 POUCH		
5		50 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	NDA016367	07/15/2019	

DEXTROSE

dextrose monohydrate injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0990-7922
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R00K)	DEXTROSE MONOHYDRATE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0990-7922-02	24 in 1 CASE	08/01/2019	
1		1 in 1 POUCH		
1		250 mL in 1 BAG; Type 0: Not a Combination Product		
2	NDC:0990-7922-03	24 in 1 CASE	08/01/2019	
2		1 in 1 POUCH		
2		500 mL in 1 BAG; Type 0: Not a Combination Product		
3	NDC:0990-7922-09	12 in 1 CASE	09/01/2019	
3		1 in 1 POUCH		
3		1000 mL in 1 BAG; Type 0: Not a Combination Product		
4	NDC:0990-7922-53	24 in 1 CASE	10/01/2019	
4		1 in 1 POUCH		
4		250 mL in 1 BAG; Type 0: Not a Combination Product		
5	NDC:0990-7922-55	18 in 1 CASE	08/01/2019	
5		1 in 1 POUCH		
5		500 mL in 1 BAG; Type 0: Not a Combination Product		
6	NDC:0990-7922-61	32 in 1 CASE	08/01/2019	
6		1 in 1 POUCH		
6		150 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	NDA016367	07/15/2019	

DEXTROSE

dextrose monohydrate injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0990-7930
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: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0990-7930-02	24 in 1 CASE	08/01/2019	
1		1 in 1 POUCH		
1		250 mL in 1 BAG; Type 0: Not a Combination Product		
2	NDC:0990-7930-03	24 in 1 CASE	08/01/2019	
2		1 in 1 POUCH		
2		500 mL in 1 BAG; Type 0: Not a Combination Product		
3	NDC:0990-7930-09	12 in 1 CASE	08/01/2019	
3		1 in 1 POUCH		
3		1000 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	07/15/2019	

Labeler - ICU Medical Inc. (118380146)

Establishment

Name	Address	ID/FEI	Business Operations
ICU MEDICAL INC.		117395980	ANALYSIS(0990-7922, 0990-7923, 0990-7930) , MANUFACTURE(0990-7922, 0990-7923, 0990-7930) , PACK(0990-7922, 0990-7923, 0990-7930) , LABEL(0990-7922, 0990-7923, 0990-7930)

