DEXTROSE AND SODIUM CHLORIDE- dextrose monohydrate and sodium chloride injection, solution
ICU Medical Inc.

Dextrose and Sodium Chloride
Injection, USP

Flexible Plastic Container

Rx only

DESCRIPTION

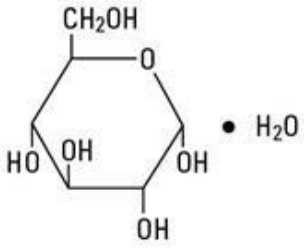
Dextrose and Sodium Chloride Injection, USP solutions are sterile and nonpyrogenic. They are large volume parenteral solutions containing various concentrations and combinations of these drugs in water for injection intended for intravenous administration.

See Table for summary of content and characteristics of these solutions.

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, nutrient and electrolyte 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:



Sodium Chloride, USP is chemically designated NaCl, a white crystalline powder freely soluble in water.

Water for Injection, USP is chemically designated H_2O.

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, carbohydrate and electrolytes.

Solutions which provide combinations of hypotonic or isotonic concentrations of dextrose and of sodium chloride are suitable for parenteral maintenance or replacement of water and electrolyte requirements with minimal carbohydrate calories.

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.

Sodium chloride in water dissociates to provide sodium (Na^+) and chloride (Cl^-) ions. Sodium (Na^+) is the principal cation of the extracellular fluid and plays a large part in the therapy of fluid and electrolyte disturbances. Chloride (Cl^-) has an integral role in buffering action when oxygen and carbon dioxide exchange occurs in the red blood cells. The distribution and excretion of sodium (Na^+) and chloride (Cl^-) are largely under the control of the kidney which maintains a balance between intake and output.

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 and sodium chloride are indicated for parenteral replenishment of fluid, minimal carbohydrate calories, and sodium chloride as required by the clinical condition of the patient.

CONTRAINDICATIONS

None known.

WARNINGS

Solutions containing sodium ions should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency and in clinical states in which there exists edema with sodium retention.

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

In patients with diminished renal function, administration of solutions containing sodium ions may result in sodium retention.

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.

Caution must be exercised in the administration of parenteral fluids, especially those containing sodium ions to patients receiving corticosteroids or corticotropin.

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

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 osmolality 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. Sodium ions are known to be substantially excreted by the kidney, and the risk of toxic reactions 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.

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.

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

Drug Interactions

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

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

Content and Characteristics

		Grams/100 mL		Per 1000 mL						
NDC No.	**Product**	**Dextrose (hydrous)**	**Sodium Chloride**	**Sodium Na^+**	**Chloride Cl^-**	**Caloric Value**	**Tonicity**	**Osmolarity mOsmol/L (calc)**	**pH**	**Container size (mL)**

0409-7924-02[*] 0990-7924-02[*]	5% Dextrose and 0.225% Sodium Chloride Inj., USP	5	0.225	38.5 mEq	38.5 mEq	170	Hypertonic	329	4.3 (3.5 to 6.5)	250
0409-7924-03[†] 0990-7924-03[*,†]	5% Dextrose and 0.225% Sodium Chloride Inj., USP	5	0.225	38.5 mEq	38.5 mEq	170	Hypertonic	329	4.3 (3.5 to 6.5)	500
0409-7924-09[*,†] 0990-7924-09[*,†]	5% Dextrose and 0.225% Sodium Chloride Inj., USP	5	0.225	38.5 mEq	38.5 mEq	170	Hypertonic	329	4.3 (3.5 to 6.5)	1000
0409-7925-03[†] 0990-7925-03[*,†]	5% Dextrose and 0.3% Sodium Chloride Inj., USP	5	0.3	51 mEq	51 mEq	170	Hypertonic	355	4.3 (3.5 to 6.5)	500
0409-7925-09[*,†] 0990-7925-09[*,†]	5% Dextrose and 0.3% Sodium Chloride Inj., USP	5	0.3	51 mEq	51 mEq	170	Hypertonic	355	4.3 (3.5 to 6.5)	1000
0409-7926-02[*] 0990-7926-02[*]	5% Dextrose and 0.45% Sodium Chloride Inj., USP	5	0.45	77 mEq	77 mEq	170	Hypertonic	406	4.3 (3.5 to 6.5)	250
0409-7926-03[†] 0990-7926-03[*,†]	5% Dextrose and 0.45% Sodium Chloride Inj., USP	5	0.45	77 mEq	77 mEq	170	Hypertonic	406	4.3 (3.5 to 6.5)	500
0409-7926-09[*,†] 0990-7926-09[*,†]	5% Dextrose and 0.45% Sodium Chloride	5	0.45	77 mEq	77 mEq	170	Hypertonic	406	4.3 (3.5 to 6.5)	1000

	Inj., USP									
0409-7941-03[†] 0990-7941-03[*,†]	5% Dextrose and 0.9% Sodium Chloride Inj., USP	5	0.9	154 mEq	154 mEq	170	Hypertonic	560	4.3 (3.5 to 6.5)	500
0409-7941-09[*,†] 0990-7941-09[*,†]	5% Dextrose and 0.9% Sodium Chloride Inj., USP	5	0.9	154 mEq	154 mEq	170	Hypertonic	560	4.3 (3.5 to 6.5)	1000

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

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.

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

Revised: August, 2020

IFU0000261

PRINCIPAL DISPLAY PANEL - 1000 mL Bag Label - NDC 0990-7924-09

1000 mL
NDC 0990-7924-09

5% DEXTROSE
and 0.225%
SODIUM CHLORIDE
Injection, USP

EACH 100 mL CONTAINS DEXTROSE, HYDROUS 5 g; SODIUM CHLORIDE 225 mg IN WATER FOR INJECTION.
ELECTROLYTES PER 1000 mL: SODIUM 38.5 mEq; CHLORIDE 38.5 mEq.
329 mOsmol/LITER (CALC).
pH 4.3 (3.5 to 6.5).
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-4424

icumedical

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

1000 mL NDC 0990-7924-09

5% DEXTROSE and 0.225% SODIUM CHLORIDE Injection, USP

EACH 100 mL CONTAINS DEXTROSE, HYDROUS 5 g; SODIUM CHLORIDE 225 mg IN WATER FOR INJECTION.
ELECTROLYTES PER 1000 mL: SODIUM 38.5 mEq; CHLORIDE 38.5 mEq.
329 mOsmol/LITER (CALC).
pH 4.3 (3.5 to 6.5).
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

LATEX

IM-4424

icumedical

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

1
2
3
4
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6
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8
9

PRINCIPAL DISPLAY PANEL - 1000 mL Bag Overwrap - NDC 0990-7924-09

2
HDPE

TO OPEN TEAR AT NOTCH

DO NOT REMOVE FROM OVERWRAP UNTIL READY FOR USE. AFTER REMOVING THE OVERWRAP, CHECK FOR MINUTE LEAKS BY SQUEEZING CONTAINER FIRMLY. IF LEAKS ARE FOUND, DISCARD SOLUTION AS STERILITY MAY BE IMPAIRED. RECOMMENDED STORAGE: ROOM TEMPERATURE (25°C). AVOID EXCESSIVE HEAT. PROTECT FROM FREEZING. SEE INSERT.
98-4321-R14-3/98

PRINCIPAL DISPLAY PANEL - 1000 mL Bag Label - NDC 0990-7925-09

1000 mL
NDC 0990-7925-09

5% DEXTROSE
and 0.3%
SODIUM CHLORIDE
Injection, USP

EACH 100 mL CONTAINS DEXTROSE, HYDROUS 5 g; SODIUM CHLORIDE 300 mg IN WATER FOR INJECTION.
ELECTROLYTES PER 1000 mL:
SODIUM 51 mEq; CHLORIDE 51 mEq.
355 mOsmol/LITER (CALC). pH 4.3 (3.5 to 6.5)
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

IMP0000052

icumedical

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

1000 mL

NDC 0990-7925-09

5% DEXTROSE and 0.3% SODIUM CHLORIDE Injection, USP

EACH 100 mL CONTAINS DEXTROSE, HYDROUS 5 g; SODIUM CHLORIDE 300 mg IN WATER FOR INJECTION. ELECTROLYTES PER 1000 mL: SODIUM 51 mEq; CHLORIDE 51 mEq. 355 mOsmol/LITER (CALC). pH 4.3 (3.5 to 6.5) 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.

(01)00309907925097

Rx ONLY

3 V CONTAINS DEHP

~~LATEX~~

IMP0000052

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

icumedical

1 2 3 4 5 6 7 8 9

PRINCIPAL DISPLAY PANEL - 1000 mL Bag Label - NDC 0990-7926-09

1000 mL
NDC 0990-7926-09

5% DEXTROSE
and 0.45%
SODIUM CHLORIDE
Injection, USP

EACH 100 mL CONTAINS DEXTROSE, HYDROUS 5 g; SODIUM CHLORIDE 450 mg IN WATER FOR INJECTION.
ELECTROLYTES PER 1000 mL: SODIUM 77 mEq; CHLORIDE 77 mEq.
406 mOsmol/LITER (CALC).
pH 4.3 (3.5 to 6.5).
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.

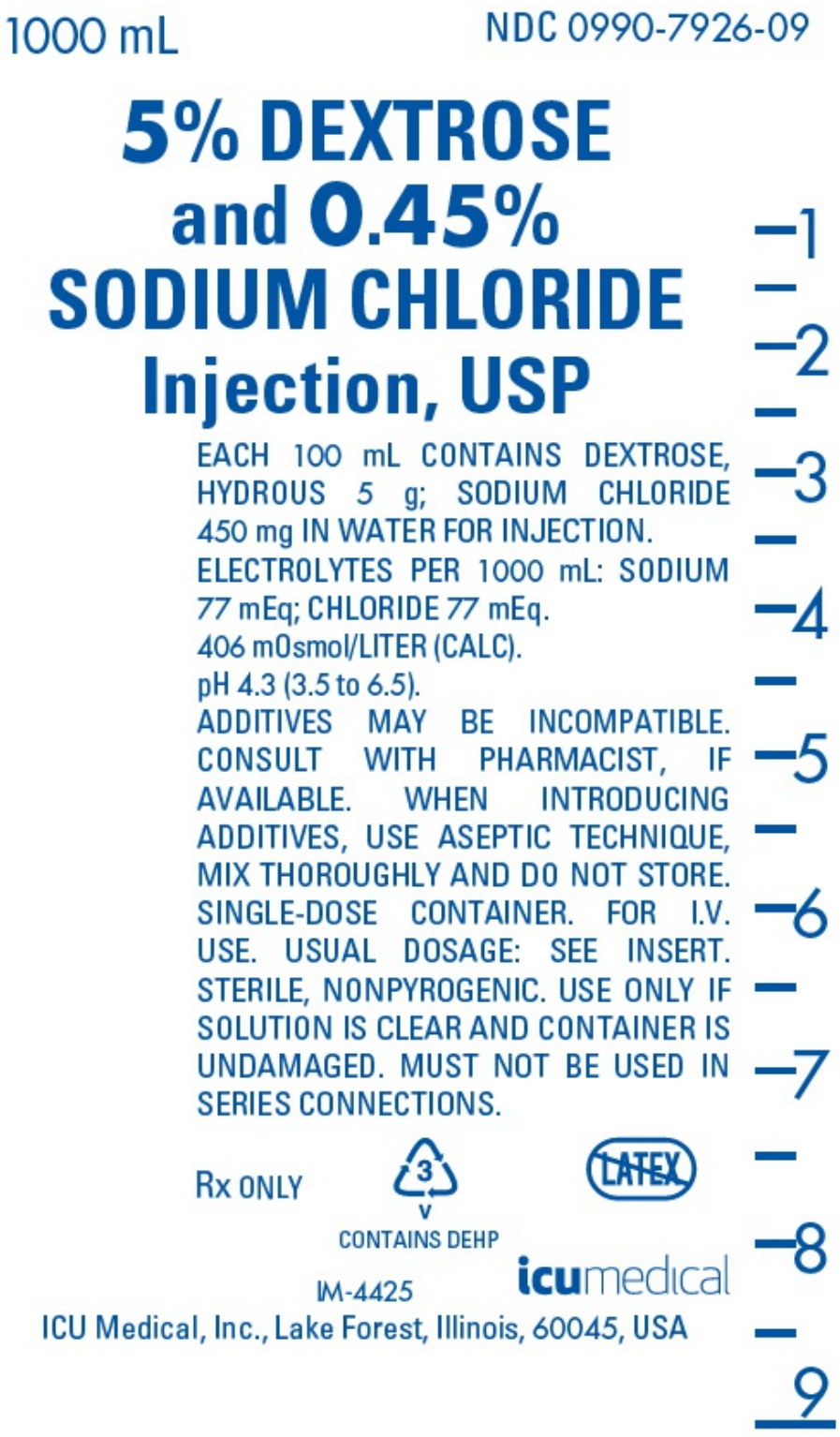
Rx ONLY

3
V
CONTAINS DEHP

icumedical

IM-4425

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



PRINCIPAL DISPLAY PANEL - 1000 mL Bag Label - NDC 0990-7941-09

1000 mL
NDC 0990-7941-09

5% DEXTROSE
and 0.9%
SODIUM CHLORIDE
Injection, USP

EACH 100 mL CONTAINS DEXTROSE,

HYDROUS 5 g; SODIUM CHLORIDE
900 mg IN WATER FOR INJECTION.
ELECTROLYTES PER 1000 mL: SODIUM
154 mEq; CHLORIDE 154 mEq.
560 mOsmol/LITER (CALC).
pH 4.3 (3.5 to 6.5)
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.

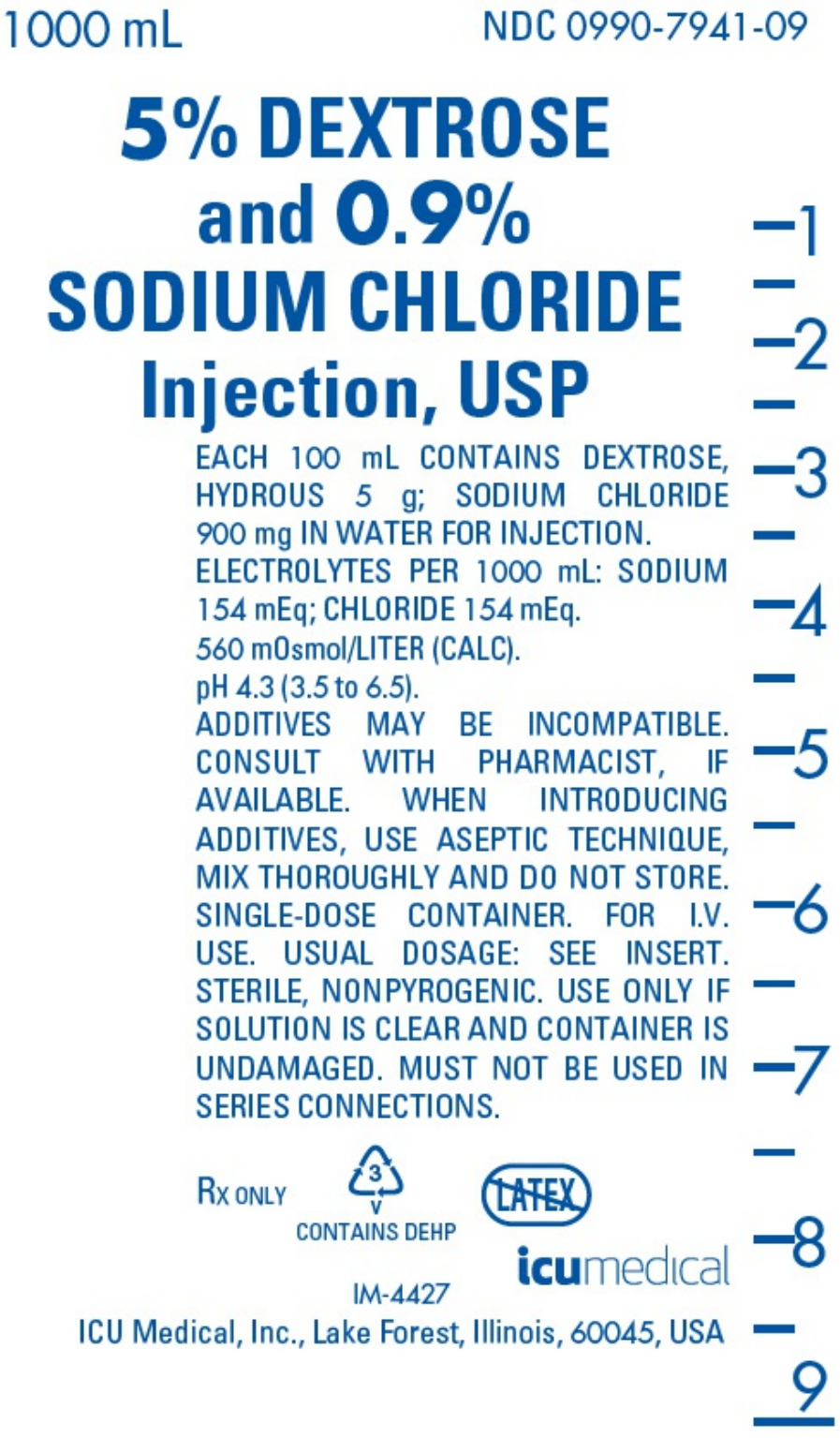
Rx ONLY

3
V
CONTAINS DEHP

icumedical

IM-4427

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



DEXTROSE AND SODIUM CHLORIDE

dextrose monohydrate and sodium chloride injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0990-7924
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	5 g in 100 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	0.225 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:0990-7924-02	24 in 1 CASE	09/01/2019	
1		1 in 1 POUCH		
1		250 mL in 1 BAG; Type 0: Not a Combination Product		
2	NDC:0990-7924-03	24 in 1 CASE	12/01/2019	
2		1 in 1 POUCH		
2		500 mL in 1 BAG; Type 0: Not a Combination Product		
3	NDC:0990-7924-09	12 in 1 CASE	12/01/2019	
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	NDA017606	09/01/2019	

DEXTROSE AND SODIUM CHLORIDE

dextrose monohydrate and sodium chloride injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0990-7925
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	5 g in 100 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	0.3 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:0990-7925-03	24 in 1 CASE	11/25/2019	
1		1 in 1 POUCH		
1		500 mL in 1 BAG; Type 0: Not a Combination Product		
2	NDC:0990-7925-09	12 in 1 CASE	12/01/2019	
2		1 in 1 POUCH		
2		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	NDA017799	09/01/2019	

DEXTROSE AND SODIUM CHLORIDE

dextrose monohydrate and sodium chloride injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0990-7926
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	5 g in 100 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	0.45 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:0990-7926-02	24 in 1 CASE	09/01/2019	
1		1 in 1 POUCH		

1		250 mL in 1 BAG; Type 0: Not a Combination Product		
2	NDC:0990-7926-03	24 in 1 CASE	12/01/2019	
2		1 in 1 POUCH		
2		500 mL in 1 BAG; Type 0: Not a Combination Product		
3	NDC:0990-7926-09	12 in 1 CASE	12/01/2019	
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	NDA017607	09/01/2019	

DEXTROSE AND SODIUM CHLORIDE

dextrose monohydrate and sodium chloride injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0990-7941
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	5 g in 100 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	0.9 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:0990-7941-03	24 in 1 CASE	12/01/2019	
1		1 in 1 POUCH		
1		500 mL in 1 BAG; Type 0: Not a Combination Product		
2	NDC:0990-7941-09	12 in 1 CASE	11/15/2019	
2		1 in 1 POUCH		
2		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	NDA017585	09/01/2019	

Labeler - ICU Medical Inc. (118380146)

Establishment

Name	Address	ID/FEI	Business Operations
ICU MEDICAL INC.		117395980	ANALYSIS(0990-7924, 0990-7925, 0990-7926, 0990-7941) , MANUFACTURE(0990-7924, 0990-7925, 0990-7926, 0990-7941) , PACK(0990-7924, 0990-7925, 0990-7926, 0990-7941) , LABEL(0990-7924, 0990-7925, 0990-7926, 0990-7941)

Revised: 10/2021 ICU Medical Inc.