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

INTRAVENOUS SOLUTIONS WITH POTASSIUM CHLORIDE

 R_x only

Potassium Chloride in 5% Dextrose and Sodium Chloride Injection, USP

Flexible Plastic Container

DESCRIPTION

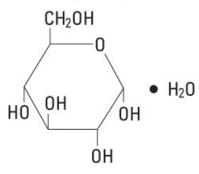
Intravenous solutions with potassium chloride (I.V. solutions with KCl) are sterile and nonpyrogenic solutions in water for injection. They are for administration by intravenous infusion only.

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

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

These solutions are parenteral fluid, nutrient and/or 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:



Potassium Chloride, USP is chemically designated KCl, a white granular powder freely soluble in water.

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 the 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 potassium chloride with carbohydrate (dextrose) and sodium chloride. See **HOW SUPPLIED** section for specific concentrations of these various solutions.

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.

Intravenous solutions containing potassium chloride are particularly intended to provide needed potassium cation (K⁺). Potassium is the chief cation of body cells (160 mEq/liter of intracellular water). It is found in low concentration in plasma and extracellular fluids (3.5 to 5.0 mEq/liter in a healthy adult). Potassium plays an important role in electrolyte balance. Normally about 80 to 90% of the potassium intake is excreted in the urine; the remainder in the stools and to a small extent, in the perspiration. The kidney does not conserve potassium well so that during fasting or in patients on a potassium-free diet, potassium loss from the body continues resulting in potassium depletion. A deficiency of either potassium or chloride will lead to a deficit of the other.

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 requirement ranges 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

These solutions are indicated in patients requiring parenteral administration of potassium chloride with minimal carbohydrate calories and sodium chloride.

CONTRAINDICATIONS

Solutions containing potassium chloride are contraindicated in diseases where high potassium levels may be encountered.

WARNINGS

Solutions which contain potassium ions should be used with great care, if at all, in patients with hyperkalemia, severe renal failure and in conditions in which potassium retention is present.

To avoid potassium intoxication, do not infuse these solutions rapidly. In patients with severe renal insufficiency or adrenal insufficiency, administration of potassium chloride may cause potassium intoxication.

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.

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

Potassium replacement therapy should be guided primarily by serial electrocardiograms. Plasma potassium levels are not necessarily indicative of tissue potassium levels.

High plasma concentrations of potassium may cause death through cardiac depression, arrhythmias or arrest.

Potassium-containing solutions should be used with caution in the presence of cardiac disease, particularly in digitalized patients or in the presence of renal disease.

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.

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

Carcinogenesis, Mutagenesis, Impairment of Fertility:

Studies with solutions from flexible plastic containers have not been performed to evaluate carcinogenic potential, mutagenic potential or effects on fertility.

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

Nursing Mothers:

Caution should be exercised when solutions from flexible plastic containers are 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 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 and potassium 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 solutions or 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.

Nausea, vomiting, abdominal pain and diarrhea have been reported with potassium therapy. The signs and symptoms of potassium intoxication include paresthesias of the extremities, flaccid paralysis, listlessness, mental confusion, weakness and heaviness of the legs, hypotension, cardiac arrhythmias, heart block, electrocardiographic abnormalities such as disappearance of P waves, spreading and slurring of the QRS complex with development of a biphasic curve and cardiac arrest.

Potassium-containing solutions are intrinsically irritating to tissues. Therefore, extreme care should be taken to avoid perivascular infiltration. Local tissue necrosis and subsequent sloughing may result if extravasation occurs. Chemical phlebitis and venospasm have also been reported.

Should perivascular infiltration occur, I.V. administration at that site should be discontinued at once. Local infiltration of the affected area with procaine hydrochloride, 1%, to which hyaluronidase may be added, will often reduce venospasm and dilute the potassium remaining in the tissues locally. Local application of heat may also be helpful.

OVERDOSAGE

In the event of potassium overdosage, discontinue the infusion immediately and institute intensive corrective therapy to reduce serum potassium levels. See **WARNINGS** and **PRECAUTIONS**.

DOSAGE AND ADMINISTRATION

These solutions should be administered only by intravenous infusion and as directed by the physician. The dose and rate of injection are dependent upon the age, weight and clinical condition of the patient. If the serum potassium level is greater than 2.5 mEq/liter, potassium should be given at a rate not to exceed 10 mEq/hour in a concentration less than 30 mEq/liter. Somewhat faster rates and greater concentrations (usually up to 40 mEq/liter) of potassium may be indicated in patients with more severe potassium deficiency. The total 24-hour dose should not generally exceed 200 mEq of potassium.

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

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:** See full directions on administration set carton.
- 4. Suspend container from hanger.
- 5. Squeeze and release drip chamber to establish proper fluid level in chamber.
- 6. Open flow control clamp and clear air from set. Close clamp.
- 7. Attach set to venipuncture device. If device is not indwelling, prime and make venipuncture.
- 8. Regulate rate of administration with flow control clamp.

WARNING: Do not use flexible container in series connections.

HOW SUPPLIED

Intravenous solutions with potassium chloride (I.V. solution with KCl) are supplied in single-dose flexible plastic containers. See Tables:

TABLE 1

Potassium Chloride in 5% Dextrose and 0.225% Sodium Chloride Inj., USP	COMPOSI	TION (g/I	_)		Арр	prox. lo	nic Conce	entrations	; (mEq/L)	
mEq Size Potassium(mL)				n Calculated Osmolarity (mOsmol/L)	•	Sodium (Na+)		m Chlorid (Cl-)	e Approxima kcal/L	nte NDC NO.
20 mEq1000) 50	2.25	1.49	370	4.2 (3.5 to 6.5)	50.5	20	58.5	170	0409- 7901- 09 ¹
20 mEq1000) 50	2.25	1.49	370	4.2 (3.5 to 6.5)		20	58.5	170	0990- 7901- 09 ¹

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.

TABLE 2

Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Inj., USP	COMPOSI	TION (g/I	-)		Арр	orox. lo	nic Conce	ntration	s (mEq/L)	
mEq Size Potassium(mL)				n Calculated Osmolarity mOsmol/L	/	Sodiun (Na+)		m Chlorid (Cl-)	le Approxima kcal/L	ate NDC NO.
10 mEq1000	50	4.5	0.745	426	4.2 (3.5 to 6.5)	77	10	87	170	0409- 7993- 09 ²
10 mEq1000	50	4.5	0.745	426	4.2 (3.5 to 6.5)	//	10	87	170	0990- 7993- 09 ^{1,2}

10 mEq 500	50	4.5	1.49	447	4.∠ (3.5 to 6.5)	77	20	97	170	0409- 7902- 03 ²
10 mEq 500	50	4.5	1.49	447	4.2 (3.5 to 6.5)	77	20	97	170	0990- 7902- 03 ^{1,2}
20 mEq1000	50	4.5	1.49	447	4.2 (3.5 to 6.5)	77	20	97	170	0409- 7902- 09 ^{1,2}
20 mEq1000	50	4.5	1.49	447	4.2 (3.5 to 6.5)	77	20	97	170	0990- 7902- 09 ^{1,2}
30 mEq1000	50	4.5	2.24	467	4.2 (3.5 to 6.5)	77	30	107	170	0409- 7903- 09 ¹
30 mEq1000	50	4.5	2.24	467	4.2 (3.5 to 6.5)	77	30	107	170	0990- 7903- 09 ¹
40 mEq1000	50	4.5	2.98	487	4.2 (3.5 to 6.5)	77	40	117	170	0409- 7904- 09 ^{1,2}
40 mEq1000	50	4.5	2.98	487	4.2 (3.5 to 6.5)	77	40	117	170	0990- 7904- 09 ^{1,2}

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.

					TABLE 3	3					
Potassium Chloride in 5% Dextrose and 0.9% Sodium Chloride Inj., USP COMPOSITION (g/L) MEq Size Dextrose, Sodium PotassiumCalculated pH SodiumPotassiumChloride Approximate NDC											
mEq Potassiun	Size	Dextrose	, Sodium	Potassiur	n Calculated Osmolarity (mOsmol/L)	рН		n Potassiu		-	ate NDC NO.
20 mEq	1000	50	9	1.49	600	4.2 (3.5 to 6.5)	154	20	174	170	0409- 7107- 09 ²
20 mEq	1000	50	9	1.49	600	4.2 (3.5 to 6.5)	154	20	174	170	0990- 7107- 09 ^{1,2}
40 mEq	1000	50	9	2.98	640	4.2 (3.5 to 6.5)	154	40	194	170	0409- 7109- 09 ²
40 mEq	1000	50	9	2.98	640	4.2 (3.5 to 6.5)	154	40	194	170	0990- 7109- 09 ^{1,2}

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.

May contain HCl for pH adjustment.

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

Revised: December, 2020

¹Manufactured by ICU Medical, Inc., Lake Forest, Illinois, 60045, USA ²Manufactured for ICU Medical, Inc., Lake Forest, Illinois, 60045, USA

IFU0000280

PRINCIPAL DISPLAY PANEL - 1000 mL Bag Label - IMP0000044

20 mEq POTASSIUM

1000 mL

NDC 0990-7107-09

20

mEq

POTASSIUM CHLORIDE

in 5% Dextrose and 0.9% Sodium Chloride Injection, USP

EACH 100 mL CONTAINS POTASSIUM CHLORIDE 149 mg; SODIUM CHLORIDE 900 mg; DEXTROSE, HYDROUS 5 g IN WATER FOR INJECTION. MAY CONTAIN HCI FOR pH ADJUSTMENT. ELECTROLYTES PER 1000 mL (NOT INCLUDING IONS FOR pH ADJUSTMENT): POTASSIUM 20 mEq; SODIUM 154 mEq; CHLORIDE 174 mEq.

600 mOsmol/LITER (CALC.) pH 4.2 (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.

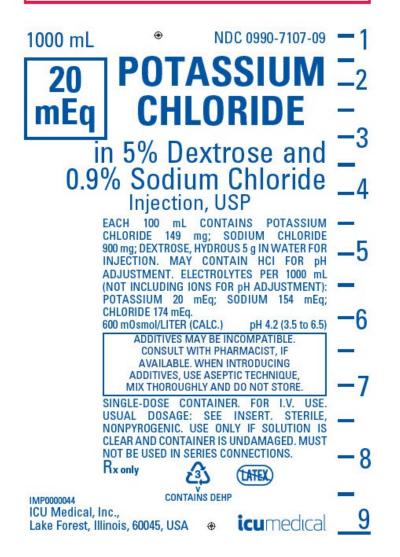
SINGLE-DOSE CONTAINER. FOR I.V. USE. USUAL DOSAGE: SEE INSERT. STERILE, NONPYROGENIC. USE ONLY IF SOLUTION IS CLEAR AND CONTAINER IS UNDAMAGED. MUST NOT BE USED IN SERIES CONNECTIONS.

Rx only

3 v

CONTAINS DEHP

IMP0000044 ICU Medical, Inc., Lake Forest, Illinois, 60045, USA icumedical



PRINCIPAL DISPLAY PANEL - 1000 mL Bag Label - IMP0000045

40 mEq POTASSIUM

1000 mL

NDC 0990-7109-09

40

mEq

POTASSIUM CHLORIDE

in 5% Dextrose and 0.9% Sodium Chloride Injection, USP

EACH 100 mL CONTAINS POTASSIUM CHLORIDE 298 mg; SODIUM CHLORIDE 900 mg; DEXTROSE, HYDROUS 5 g IN WATER FOR INJECTION. MAY CONTAIN HCI FOR pH ADJUSTMENT. ELECTROLYTES PER 1000 mL (NOT INCLUDING IONS FOR pH ADJUSTMENT): POTASSIUM 40 mEq; SODIUM 154 mEq; CHLORIDE 194 mEq. 640 mOsmol/LITER (CALC.) pH 4.2 (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.

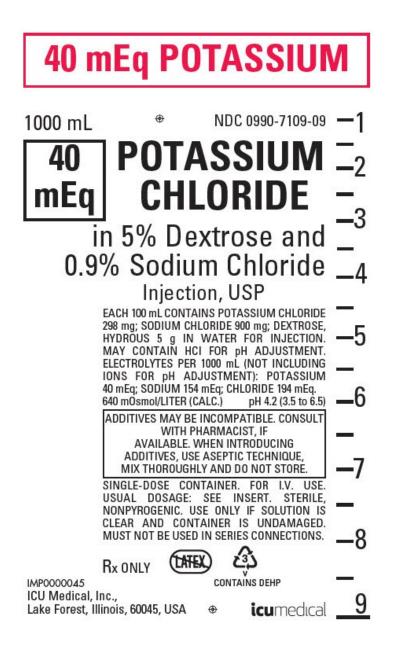
SINGLE-DOSE CONTAINER. FOR I.V. USE. USUAL DOSAGE: SEE INSERT. STERILE, NONPYROGENIC. USE ONLY IF SOLUTION IS CLEAR AND CONTAINER IS UNDAMAGED. MUST NOT BE USED IN SERIES CONNECTIONS.

Rx ONLY

3 V

CONTAINS DEHP

IMP0000045 ICU Medical, Inc., Lake Forest, Illinois, 60045, USA icumedical



PRINCIPAL DISPLAY PANEL - 1000 mL Bag Label - IM-4420

30 mEq POTASSIUM

1000 mL

NDC 0990-7903-09

30 mEq

POTASSIUM

in 5% Dextrose and 0.45% Sodium Chloride Injection, USP

EACH 100 mL CONTAINS POTASSIUM CHLORIDE 224 mg; SODIUM CHLORIDE 450 mg; DEXTROSE, HYDROUS 5 g IN WATER FOR INJECTION. MAY CONTAIN HCI FOR pH ADJUSTMENT. ELECTROLYTES PER 1000 mL (NOT INCLUDING IONS FOR pH ADJUSTMENT): POTASSIUM 30 mEq; SODIUM 77 mEq; CHLORIDE 107 mEq.

467 mOsmol/LITER (CALC.) pH 4.2 (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.

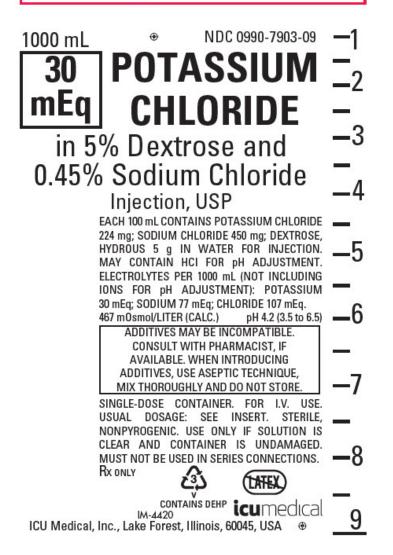
SINGLE-DOSE CONTAINER. FOR I.V. USE. USUAL DOSAGE: SEE INSERT. STERILE, NONPYROGENIC. USE ONLY IF SOLUTION IS CLEAR AND CONTAINER IS UNDAMAGED. MUST NOT BE USED IN SERIES CONNECTIONS.

Rx ONLY

3 v

CONTAINS DEHP

IM-4420 ICU Medical, Inc., Lake Forest, Illinois, 60045, USA icumedical



PRINCIPAL DISPLAY PANEL - 1000 mL Bag Label - IM-4421

40 mEq POTASSIUM

1000 mL

NDC 0990-7904-09

40

mEq

POTASSIUM CHLORIDE

in 5% Dextrose and 0.45% Sodium Chloride Injection, USP

EACH 100 mL CONTAINS POTASSIUM CHLORIDE 298 mg; SODIUM CHLORIDE 450 mg; DEXTROSE, HYDROUS 5 g IN WATER FOR INJECTION. MAY CONTAIN HCI FOR pH ADJUSTMENT. ELECTROLYTES PER 1000 mL (NOT INCLUDING IONS FOR pH ADJUSTMENT): POTASSIUM 40 mEq; SODIUM 77 mEq; CHLORIDE 117 mEq.

487 mOsmol/LITER (CALC.) pH 4.2 (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.

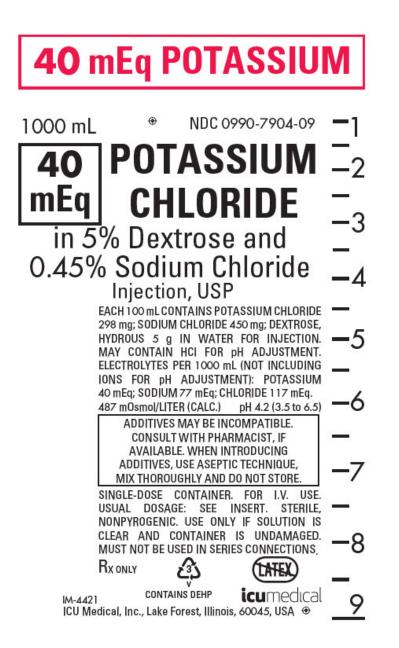
Rx ONLY

3 v

CONTAINS DEHP

IM-4421

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



1000 mL

NDC 0990-7993-09

10 mEq

POTASSIUM CHLORIDE

in 5% Dextrose and 0.45% Sodium Chloride Injection, USP

EACH 100 mL CONTAINS POTASSIUM CHLORIDE 74.5 mg; SODIUM CHLORIDE 450 mg; DEXTROSE, HYDROUS 5 g IN WATER FOR INJECTION. MAY CONTAIN HCI FOR pH ADJUSTMENT.

ELECTROLYTES PER 1000 mL (NOT INCLUDING IONS FOR pH ADJUSTMENT): POTASSIUM 10 mEq; SODIUM 77 mEq; CHLORIDE 87 mEq.

426 mOsmol/LITER (CALC.) pH 4.2 (3.5 to 6.5)

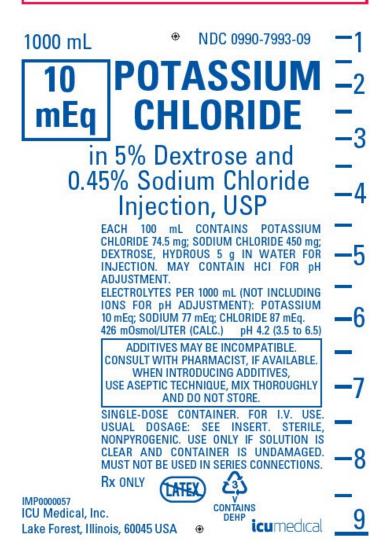
ADDITIVES MAY BE INCOMPATIBLE. CONSULT WITH PHARMACIST, IF AVAILABLE. WHEN INTRODUCING ADDITIVES, USE ASEPTIC TECHNIQUE, MIX THOROUGHLY AND DO NOT STORE.

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

IMP0000057 ICU Medical, Inc. Lake Forest, Illinois, 60045 USA icumedical



PRINCIPAL DISPLAY PANEL - 1000 mL Bag Label - IM-4418

20 mEq POTASSIUM

1000 mL

NDC 0990-7901-09

20 mEq

POTASSIUM CHLORIDE in 5% Dextrose and 0.225% Sodium Chloride Injection, USP

EACH 100 mL CONTAINS POTASSIUM CHLORIDE 149 mg; SODIUM CHLORIDE 225 mg; DEXTROSE, HYDROUS 5 g IN WATER FOR INJECTION. MAY CONTAIN HCI FOR pH ADJUSTMENT. ELECTROLYTES PER 1000 mL (NOT INCLUDING IONS FOR pH ADJUSTMENT): POTASSIUM 20 mEq; SODIUM 38.5 mEq; CHLORIDE 58.5 mEq.

370 mOsmol/LITER (CALC.) pH 4.2 (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.

©HOSPIRA 2004 IM-0057 (4/04) PRINTED IN USA HOSPIRA, INC., LAKE FOREST, IL 60045 USA

Rx ONLY

3 V

CONTAINS DEHP

IM-4418 ICU Medical, Inc., Lake Forest, Illinois, 60045, USA icumedical



PRINCIPAL DISPLAY PANEL - 500 mL Bag Label - IM-4447

10 mEq POTASSIUM

500 mL

NDC 0990-7902-03

10 mEq

POTASSIUM CHLORIDE in 5% Dextrose and 0.45% Sodium Chloride Inj., USP

EACH 100 mL CONTAINS POTASSIUM CHLORIDE 149 mg; SODIUM CHLORIDE 450 mg; DEXTROSE, HYDROUS 5 g IN WATER FOR INJECTION. MAY CONTAIN HCI FOR pH ADJUSTMENT. ELECTROLYTES PER 1000 mL (NOT INCLUDING IONS FOR pH ADJUSTMENT): POTASSIUM 20 mEq; SODIUM 77 mEq; CHLORIDE 97 mEq. 447 mOsmol/LITER (CALC.) pH 4.2 (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.

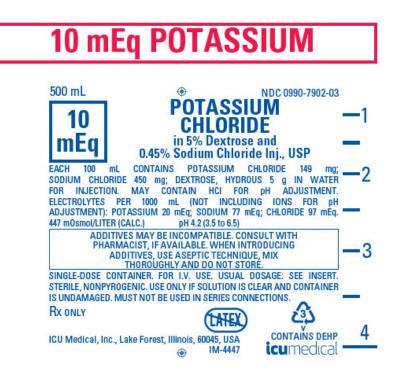
SINGLE-DOSE CONTAINER. FOR I.V. USE. USUAL DOSAGE: SEE INSERT. STERILE, NONPYROGENIC. USE ONLY IF SOLUTION IS CLEAR AND CONTAINER IS UNDAMAGED. MUST NOT BE USED IN SERIES CONNECTIONS.

Rx ONLY

3 v

CONTAINS DEHP

ICU Medical, Inc., Lake Forest, Illinois, 60045, USA IM-4447 icumedical



PRINCIPAL DISPLAY PANEL - Overwrap

TO OPEN TEAR AT NOTCH

2 HDPE

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

TO OPEN TEAR AT NOTCH



DO NOT REMOVE FROM OVERWRAP UNTIL READY FOR USE. AFTER REMOVING THE OVERWRAP, CHECK FOR MINUTE LEAKS BY SOUEEZING 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

Pr	roduct Infor	mation					
Pr	oduct Type		HUMAN PRESCRIPTION DRUG	Item Code (S	Source)	NDC	:0990-7107
Ro	oute of Admini	stration	INTRAVENOUS				
Ac	tive Ingredi	ent/Active	Moiety				
		Ing	gredient Name		Basi: Strer		Strengt
	XTROSE MONO II:5SL0G7R0OK)	HYDRATE (UNI	I: LX22YL083G) (ANHYDROUS DEXT	ROSE -	DEXTROS MONOHYE	E	50 g in 1000 m
	DIUM CHLORID		7IQ8X) (SODIUM CATION - UNII:LYR4	M0NH37,	SODIUM CHLORIDE		9 g in 1000 m
			0YQ98I10) (POTASSIUM CATION - UNII:Q32ZN48698)		POTASSIL CHLORIDE		1.49 g in 1000 m
In	active Ingre	dients					
			Ingredient Name		Str	ength	
łY	ATER (UNII: 059Q DROCHLORIC A	,	17582CB)				
Ра		CID (UNII: QTT		Marketing			-
нү Ра #	DROCHLORIC A Ackaging Item Code NDC:0990-7107-	CID (UNII: QTT Pa	17582CB) ckage Description	Date			eting End Date
нү Ра #	DROCHLORIC A Ackaging Item Code	CID (UNII: QTT Pa 12 in 1 CASE		-			-
нү Ра # 1	DROCHLORIC A Ackaging Item Code NDC:0990-7107-	CID (UNII: QTT Pa 12 in 1 CASE 1 in 1 POUCH		Date			-
нү Ра # 1	DROCHLORIC A Ackaging Item Code NDC:0990-7107-	CID (UNII: QTT Pa 12 in 1 CASE 1 in 1 POUCH 1000 mL in 1	ckage Description	Date			-
нү Ра 1 1	DROCHLORIC A Ackaging Item Code NDC:0990-7107-	CID (UNII: QTT Pa 12 in 1 CASE 1 in 1 POUCH 1000 mL in 1 Product	ckage Description BAG; Type 0: Not a Combination	Date			eting End Date
нү Ра 1 1	DROCHLORIC A Ackaging Item Code NDC:0990-7107- 09	Pa 12 in 1 CASE 1 in 1 POUCH 1000 mL in 1 Product	ckage Description BAG; Type 0: Not a Combination	Date	g Start		-
нү Ра 1 1	DROCHLORIC A ackaging Item Code NDC:0990-7107- 09 arketing Category	Pa 12 in 1 CASE 1 in 1 POUCH 1000 mL in 1 Product	ckage Description BAG; Type 0: Not a Combination iion tion Number or Monograph Citation	Date 02/01/2020 Marketing	g Start		Date ceting End
нү Ра 1 1	DROCHLORIC A ackaging Item Code NDC:0990-7107- 09 arketing Category	Pa 12 in 1 CASE 1 in 1 POUCH 1000 mL in 1 Product Informat Applica	ckage Description BAG; Type 0: Not a Combination iion tion Number or Monograph Citation	Date 02/01/2020 Marketing Dat	g Start		Date ceting End
HY Pa 1 1 1 ND	DROCHLORIC A ackaging Item Code NDC:0990-7107- 09 Marketing Category A	CID (UNII: QTT Pa 12 in 1 CASE 1 in 1 POUCH 1000 mL in 1 Product Informat Applica NDA019691	ckage Description BAG; Type 0: Not a Combination ion tion Number or Monograph Citation	Date 02/01/2020 Marketing Dat 01/25/2020	g Start e	Mark	Date ceting End Date
HY Pa 1 1 1 ND	DROCHLORIC A ackaging Item Code NDC:0990-7107- 09 Marketing Category A DTASSIUM	CID (UNII: QTT Pa 12 in 1 CASE 1 in 1 POUCH 1000 mL in 1 Product Informat Applica NDA019691	ckage Description BAG; Type 0: Not a Combination ion tion Number or Monograph Citation	Date 02/01/2020 Marketing Dat 01/25/2020	g Start e	Mark	Date ceting Enc Date
HY Pa 1 1 1 ND	DROCHLORIC A ackaging Item Code NDC:0990-7107- 09 Marketing Category A DTASSIUM	CID (UNII: QTT Pa 12 in 1 CASE 1 in 1 POUCH 1000 mL in 1 Product Informat Applica NDA019691	ckage Description BAG; Type 0: Not a Combination ion tion Number or Monograph Citation	Date 02/01/2020 Marketing Dat 01/25/2020	g Start e	Mark	Date ceting Enc Date
HY Pa 1 1 1 1 M ND	DROCHLORIC A ackaging Item Code NDC:0990-7107- 09 Marketing Category A DTASSIUM	CID (UNII: QTT Pa 12 in 1 CASE 1 in 1 POUCH 1000 mL in 1 Product Informat Applica NDA019691	ckage Description BAG; Type 0: Not a Combination ion tion Number or Monograph Citation	Date 02/01/2020 Marketing Dat 01/25/2020	g Start e	Mark	Date ceting Enc Date
Pa # 1 1 1 M ND, PC	DROCHLORIC A ackaging Item Code NDC:0990-7107- 09 Arketing Category A DTASSIUM xtrose monohy	CID (UNII: QTT Pa 12 in 1 CASE 1 in 1 POUCH 1000 mL in 1 Product Informat Applica NDA019691	ckage Description BAG; Type 0: Not a Combination ion tion Number or Monograph Citation	Date 02/01/2020 Marketing Dat 01/25/2020	g Start e IM CH on, solut	Mark LORII	Date ceting End Date

Active Ingredient/Active Moiety **Basis of Ingredient Name** Strength Strength DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE -DEXTROSE 50 g

1 1 1	NDC:0990-7109- 09	12 in 1 CASE 1 in 1 POUCH 1000 mL in 1 BAG; Type 0: Not a Combination Product Information Application Number or Monograph Citation	01/25/2020	g Start	Mark	Jate reting End Date
1 1 1	09	1 in 1 POUCH 1000 mL in 1 BAG; Type 0: Not a Combination Product				Jate
1		1 in 1 POUCH 1000 mL in 1 BAG; Type 0: Not a Combination				Jate
1		1 in 1 POUCH 1000 mL in 1 BAG; Type 0: Not a Combination				Date
1		1 in 1 POUCH				Date
		12 in 1 CASE			L	Date
"			Dute		L	Date
#	ltem Code	Package Description	Marketing Date		rt Marketing En Date	
Pa	ackaging					
ΗY	DROCHLORIC A	CID (UNII: QTT17582CB)				
w	ATER (UNII: 059Q	-			U	
	active mgre	Ingredient Name			Str	ength
In	active Ingre	dients				
UN		RIDE (UNII: 660YQ98I10) (POTASSIUM CATION - CHLORIDE ION - UNII:Q32Z N48698)		POTASSIU CHLORIDE		2.98 g in 1000 m
	ILORIDE ION - UNI	E (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR I:Q32ZN48698)	4M0NH37,	SODIUM CHLORIDE		9 g in 1000 m
CH PC	DIUM CHLORID		414011107			•

POTASSIUM CHLORIDE IN DEXTROSE AND SODIUM CHLORIDE

dextrose monohydrate, sodium chloride, and potassium chloride injection, solution

Product Information	Product Information								
Product Type	HUMAN PRESCRIPTION DRUG	ltem Code (Source)	NDC:0990-7903						
Route of Administration	INTRAVENOUS								

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:55L0G7R00K)	DEXTROSE MONOHYDRATE	50 g in 1000 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	4.5 g in 1000 mL
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295053K152, CHLORIDE ION - UNII:Q32ZN48698)	POTASSIUM CHLORIDE	2.24 g in 1000 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Package Description Marketing Start Date Marketing End Date 1 NDC:0990-7903-09 12 in 1 CASE 02/01/2020 1 1 in 1 POUCH 1 1 1000 mL in 1 BAG; Type 0: Not a Combination Product Image: Comparison of Comparison of Combination Product

Marketing Information									
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date						
NDA	NDA018362	02/01/2020							
DOTACCIUM	CHI ODIDE IN DEVTROSE AN								

POTASSIUM CHLORIDE IN DEXTROSE AND SODIUM CHLORIDE

dextrose monohydrate, sodium chloride, and potassium chloride injection, solution

Ingredient Name Basis of Strength Strength DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - DIMI:S5L0G7R00K) DEXTROSE - MONOHYDRATE DEXTROSE - MONOHYDRATE 50 g in 1000 SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4MONH37, CHLORIDE ION - UNII:Q32ZN48698) SODIUM CHLORIDE (UNII: 660YQ98110) (POTASSIUM CATION - UNII:295053K152, CHLORIDE ION - UNII:Q32Z N48698) POTASSIUM CHLORIDE 2.98 g in 1000 POTASSIUM CHLORIDE (UNII: 660YQ98110) (POTASSIUM CATION - UNII:295053K152, CHLORIDE ION - UNII:Q32Z N48698) POTASSIUM CHLORIDE 2.98 g in 1000 PACKage Description Strength PACKagging Marketing Start Date Marketing Er Date PACKaging 12 in 1 CASE 02/01/2020 I in 1 POUCH 1 NDC:0990-7904- 1 in 1 POUCH 12 in 1 POUCH 02/01/2020 I in 1 POUCH		oduct Type		HUMAN PRESCRIPTION DRUG	Item Code (S	Source)	NDC	2:0990-7904
Ingredient Name Strength Strength DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - NNII:5SL0G7R00K) DEXTROSE - MONOHYDRATE DEXTROSE - MONOHYDRATE DEXTROSE - MONOHYDRATE S0 g in 1000 SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4MONH37, CHLORIDE ION - UNII:Q32ZN48698) SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4MONH37, CHLORIDE ION - UNII:Q32ZN48698) SODIUM CHLORIDE (UNII: 660YQ98110) (POTASSIUM CATION - POTASSIUM CHLORIDE (UNII: 0590F0KOR) 2.98 g in 1000 NATER (UNII: 0590F0KOR) Ingredient Name Strength NATER (UNII: 0590F0KOR) Information - Information (UNII: QTT17582CB) Strength Package Description Marketing Start Date Marketing Er Date Marketing Er Date 1 NDC:0990-7904- (9) 12 in 1 CASE 02/01/2020 In 1000	Ro	ute of Admini	stration	INTRAVENOUS		-		
Ingredient Name Basis of Strength Strength DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - JUNI:SSL0G7ROOK) DEXTROSE MONOHYDRATE 50 g in 1000 SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4MONH37, CHLORIDE (ION - UNII:Q32ZN48698) SODIUM CHLORIDE 4.5 g in 1000 POTASSIUM CHLORIDE (UNII: 650YQ98120) (POTASSIUM CATION - UNII:S95053K152, CHLORIDE ION - UNII:Q32ZN48698) POTASSIUM CHLORIDE 2.98 g in 1000 POTASSIUM CHLORIDE (UNII: 660YQ98120) (POTASSIUM CATION - UNII:Q32ZN48698) POTASSIUM CHLORIDE 2.98 g in 1000 POTASSIUM CHLORIDE (UNII: 670YD98120) (POTASSIUM CATION - UNII:Q32ZN48698) POTASSIUM CHLORIDE 2.98 g in 1000 PACKaging Ingredient Name Strength Date PACKaging Item Code Package Description Marketing Start Date I NDC:0990-7904- 12 in 1 CASE 02/01/2020 Image In 1 POUCH I 1000 ml in 1 POUCH 1000 ml in 1 POUCH Image In 1 POUCH								
Ingredient Name Strength Strength DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R00K) DEXTROSE - MONOHYDRATE DEXTROSE - MONOHYDRATE DEXTROSE - MONOHYDRATE DEXTROSE - MONOHYDRATE S0 g in 1000 SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4MONH37, CHLORIDE ION - UNII:Q32Z N48698) SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4MONH37, CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295053K152, CHLORIDE ION - UNII:Q32Z N48698) SODIUM CATION - POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - CHLORIDE ION - UNII:Q32Z N48698) 2.98 g in 1000 Inactive Ingredients Ingredient Name Strength MATER (UNII: 059QF0K00R) HYDROCHLORIC ACID (UNII: QTT17582CB) Strength # Item Code Package Description Marketing Start Date 1 NDC:0990-7904- 09 12 in 1 CASE 02/01/2020 1 In 1 POUCH In 1 POUCH 1 1000 mL in 1 BGG: Turo 0: Not a Combination In 1 CASE	Ac	tive Ingredi	ent/Active	Moiety		_		
Image: Second			Ing	gredient Name				Streng
Image: CHLORIDE ION - UNII:032Z N48698) CHLORIDE in 1000 POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - JNII:295053K152, CHLORIDE ION - UNII:032Z N48698) POTASSIUM CHLORIDE 2.98 g in 1000 Imactive Ingredients Ingredient Name Strength MATER (UNII: 059QF0K00R) Strength Strength HYDROCHLORIC ACID (UNII: QTT17582CB) Marketing Start Date Marketing Er Date # Item Code Package Description Marketing Start Date Marketing Er Date 1 NDC:0990-7904- 09 12 in 1 CASE 02/01/2020 Image: Chloride International Internation International			HYDRATE (UN	II: LX22YL083G) (ANHYDROUS DEX	FROSE -			50 g in 1000 r
JNII: 295053K152, CHLORIDE ION - UNII: Q32Z N48698) CHLORIDE in 1000 Ingredients Strength NATER (UNII: 059QF0K00R) HYDROCHLORIC ACID (UNII: QTT17582CB) Packaging Marketing Start Date Marketing Start Date NDC:0990-7904- 19 12 in 1 CASE 02/01/2020 1 In 1 POUCH In 1 POUCH In 1 POUCH					4M0NH37,			4.5 g in 1000 r
Ingredients Ingredient Name Strength WATER (UNII: 059QF0K00R) HYDROCHLORIC ACID (UNII: QTT17582CB) Packaging Marketing Start Date Marketing Er Date Item Code Package Description Marketing Start Date Marketing Er Date 1 NDC:0990-7904- 12 in 1 CASE 02/01/2020 1 in 1 POUCH 1000 ml in 1 BAG: Type 0: Net a Combination	PO'	TASSIUM CHLO	RIDE (UNII: 66	0YQ98I10) (POTASSIUM CATION -				2.98 g
Ingredient Name Strength NATER (UNII: 059QF0K00R) 5 HYDROCHLORIC ACID (UNII: QTT17582CB) 5	7181	1.293033KI32, C	TILORIDE ION -	0111.Q322146098)		CHLORIE		111 1000 1
Ingredient Name Strength NATER (UNII: 059QF0K00R)								
WATER (UNII: 059QF0K00R) HYDROCHLORIC ACID (UNII: QTT17582CB) Packaging # Item Code Package Description Marketing Start Date Marketing Er Date 1 NDC:0990-7904- 09 12 in 1 CASE 02/01/2020 02/01/2020 1 In 1 POUCH 1000 mL in 1 PAG: Type 0: Net a Combination 02/01/2020			dianta					
HydrochLoric Acid (UNII: QTT17582CB) Packaging Item Code Package Description Marketing Start Date Marketing En Date I NDC:0990-7904- 09 12 in 1 CASE 02/01/2020 02/01/2020 I 1000 ml in 1 PAG: Type 0: Net a Combination 0100 ml in 1 PAG: Type 0: Net a Combination 02/01/2020	na	active Ingre	aients					
Packaging # Item Code Package Description Marketing Start Date Marketing En Date I NDC:0990-7904- 09 12 in 1 CASE 02/01/2020 02/01/2020 I 1 in 1 POUCH 1000 ml in 1 RAG: Type 0: Net a Combination 02/01/2020				Ingredient Name			St	rength
NDC:0990-7904- 09 12 in 1 CASE 02/01/2020 I 1 in 1 POUCH Image: Complexity of the second sec	NA	ATER (UNII: 059Q	F0KO0R)	-			St	rength
109 12 IN 1 CASE 02/01/2020 1 1 in 1 POUCH 1000 mL in 1 RAG: Type 0: Not a Combination	W A HYI	ATER (UNII: 059Q DROCHLORIC A	F0KO0R)	-			St	rength
1000 mL in 1 RAC: Type 0: Net a Combination	ма нүі Ра	ATER (UNII: 059Q DROCHLORIC A	FOKOOR) C ID (UNII: QTT	17582CB)			Mark	eting En
1000 mL in 1 BAG: Type 0: Not a Combination	Pa #	ATER (UNII: 059Q DROCHLORIC A DROCHLORIC A Item Code NDC:0990-7904-	FOKOOR) CID (UNII: QTT Pa	17582CB)	Date		Mark	eting En
Product	₩ A HYI Pa #	ATER (UNII: 059Q DROCHLORIC A DROCHLORIC A Item Code NDC:0990-7904-	FOKOOR) CID (UNII: QTT Pa 12 in 1 CASE	17582CB)	Date		Mark	eting En
	WA HYI Pa #	ATER (UNII: 059Q DROCHLORIC A DROCHLORIC A Item Code NDC:0990-7904-	F0KO0R) CID (UNII: QTT Pa 12 in 1 CASE 1 in 1 POUCH 1000 mL in 1	17582CB)	Date		Mark	eting En
	WA HYI Pa #	ATER (UNII: 059Q DROCHLORIC A DROCHLORIC A Item Code NDC:0990-7904-	F0KO0R) CID (UNII: QTT Pa 12 in 1 CASE 1 in 1 POUCH 1000 mL in 1	17582CB)	Date		Mark	eting En
Marketing Information	WA HYI # 1	ATER (UNII: 059Q DROCHLORIC A Ickaging Item Code NDC:0990-7904- 09	F0KO0R) CID (UNII: QTT Pa 12 in 1 CASE 1 in 1 POUCH 1000 mL in 1 Product	17582CB) Ackage Description BAG; Type 0: Not a Combination	Date		Mark	eting En
MarketingApplicationMarketing StartMarketing EndCategoryCitationDateDate	WA 1YI Pa #	ATER (UNII: 059Q DROCHLORIC A Inckaging Item Code NDC:0990-7904- 09 arketing	F0KO0R) CID (UNII: QTT Pa 12 in 1 CASE 1 in 1 POUCH 1000 mL in 1 Product	17582CB) Inckage Description BAG; Type 0: Not a Combination Cion	Date 02/01/2020 Marketing	g Start	Mark	eting En Date keting En
Marketing Application Number or Monograph Marketing Start Marketing E	WA HYI Pa # 1 [(1	ATER (UNII: 059Q DROCHLORIC A Inckaging Item Code NDC:0990-7904- 09 arketing Category	FOKOOR) CID (UNII: QTT Pa 12 in 1 CASE 1 in 1 POUCH 1000 mL in 1 Product	17582CB) Ickage Description BAG; Type 0: Not a Combination Citation	Date 02/01/2020 Marketing Date	g Start	Mark	eting En Date keting En
	WA HYI Pa #	ATER (UNII: 059Q DROCHLORIC A DROCHLORIC A Item Code NDC:0990-7904-	FOKOOR) CID (UNII: QTT Pa	17582CB)	Date		Mark	etin
	WA HYI Pa # 1 [ATER (UNII: 059Q DROCHLORIC A DROCHLORIC A Item Code NDC:0990-7904-	F0KO0R) CID (UNII: QTT Pa 12 in 1 CASE 1 in 1 POUCH 1000 mL in 1	17582CB)	Date		Mark	eting En
	WA HYI Pa 1 [ATER (UNII: 059Q DROCHLORIC A DROCHLORIC A Item Code NDC:0990-7904-	F0KO0R) CID (UNII: QTT Pa 12 in 1 CASE 1 in 1 POUCH 1000 mL in 1	17582CB)	Date		Mark	eting En
	WA HYI Pa 1 [ATER (UNII: 059Q DROCHLORIC A DROCHLORIC A Item Code NDC:0990-7904-	F0KO0R) CID (UNII: QTT Pa 12 in 1 CASE 1 in 1 POUCH 1000 mL in 1	17582CB)	Date		Mark	eting En
Marketing Information	WA 1YI Pa #	ATER (UNII: 059Q DROCHLORIC A Ickaging Item Code NDC:0990-7904- 09	F0KO0R) CID (UNII: QTT Pa 12 in 1 CASE 1 in 1 POUCH 1000 mL in 1 Product	17582CB) Ackage Description BAG; Type 0: Not a Combination	Date		Mark	eting En
Marketing Application Number or Monograph Marketing Start Marketing E	WA HYI # 1	ATER (UNII: 059Q DROCHLORIC A Inckaging Item Code NDC:0990-7904- 09 arketing	F0KO0R) CID (UNII: QTT Pa 12 in 1 CASE 1 in 1 POUCH 1000 mL in 1 Product	17582CB) Inckage Description BAG; Type 0: Not a Combination Cion	Date 02/01/2020 Marketing	g Start	Mark	eting En Date
Marketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End Date		ATER (UNII: 059Q DROCHLORIC A Inckaging Item Code NDC:0990-7904- 09 arketing Category	FOKOOR) CID (UNII: QTT Pa 12 in 1 CASE 1 in 1 POUCH 1000 mL in 1 Product	17582CB) Ickage Description BAG; Type 0: Not a Combination Citation	Date 02/01/2020 Marketing Date	g Start	Mark	eting En Date

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0990-7993
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:55L0G7R00K)	DEXTROSE MONOHYDRATE	50 g in 1000 mL	
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	4.5 g in 1000 mL	
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION -	POTASSIUM	0.745 g	

JNII:295053K152, C	CHLORIDE ION -	UNII:Q32Z N48698)		CHLORID	E	in 1000 ml
nactive Ingre	dients					
		Ingredient Name			St	rength
VATER (UNII: 059Q IYDROCHLORIC A		17592(P)				
IT DROCHLORIC A		[/302CB)				
Packaging						
tem Code	Pa	ckage Description	Marketing Date		Mark	eting End Date
NDC:0990-7993-	12 in 1 CASE		02/01/2020			
	1 in 1 POUCH					
	1000 mL in 1 E Product	BAG; Type 0: Not a Combination				
	Troduct					
Marketing	Informat	ion				
Marketing Category	Applicat	tion Number or Monograph Citation	Marketin Dat		Mar	keting End Date
IDA	NDA018362		02/01/2020			
extrose monoh	ydrate, sodiu	DE IN DEXTROSE AI m chloride, and potassium c		-	-	DE
extrose monoh Product Infor	ydrate, sodiu	m chloride, and potassium c	hloride injecti	on, solu	ition	
extrose monoh Product Infor Product Type	ydrate, sodiu mation	m chloride, and potassium c		on, solu	ition	
extrose monoh Product Infor Product Type	ydrate, sodiu mation	m chloride, and potassium c	hloride injecti	on, solu	ition	
extrose monoh Product Infor Product Type Route of Admini	ydrate, sodiu mation istration	m chloride, and potassium c HUMAN PRESCRIPTION DRUG INTRAVENOUS	hloride injecti	on, solu	ition	DE C:0990-7901
extrose monoh Product Infor Product Type Route of Admini	ydrate, sodiu mation istration ient/Active	m chloride, and potassium c HUMAN PRESCRIPTION DRUG INTRAVENOUS	hloride injecti	on, solu Source)	ition	C:0990-7901
extrose monoh Product Infor Product Type Route of Admini	ydrate, sodiu mation istration ient/Active Ing	m chloride, and potassium c HUMAN PRESCRIPTION DRUG INTRAVENOUS Moiety gredient Name	hloride injecti Item Code (S	on, solu Source) Bas Stre	ntion NDC	C:0990-7901
extrose monoh Product Infor Product Type Route of Admini Active Ingredi DEXTROSE MONO JNII:5SLOG7ROOK)	ydrate, sodiu mation istration ient/Active Ing HYDRATE (UNII	m chloride, and potassium c HUMAN PRESCRIPTION DRUG INTRAVENOUS Moiety gredient Name : LX22YL083G) (ANHYDROUS DEXT	hloride injecti Item Code (S	on, solu Source) Bas Stre DEXTRO: MONOHY	ition NDC sis of ength SE (DRATE	50 g in 1000 n
extrose monoh Product Infor Product Type Route of Admini Active Ingredi DEXTROSE MONO JNII:5SL0G7R00K) SODIUM CHLORID	ydrate, sodiu mation istration ient/Active Ing HYDRATE (UNII E (UNII: 451W47	m chloride, and potassium c HUMAN PRESCRIPTION DRUG INTRAVENOUS Moiety gredient Name : LX22YL083G) (ANHYDROUS DEXT 21Q8X) (SODIUM CATION - UNII:LYR4	hloride injecti Item Code (S	on, solu Source) Bas Stre DEXTRO	ition NDC sis of ength SE (DRATE	C:0990-7901 Strengt 50 g in 1000 m 2.25 g
extrose monoh Product Infor Product Type Route of Admini Active Ingredi DEXTROSE MONO JNII:5SL0G7R00K) SODIUM CHLORID CHLORIDE ION - UNI POTASSIUM CHLO	ydrate, sodiu mation istration ient/Active Ing HYDRATE (UNII E (UNII: 451W47 I:Q32ZN48698) IRIDE (UNII: 660	m chloride, and potassium c HUMAN PRESCRIPTION DRUG INTRAVENOUS Moiety gredient Name : LX22YL083G) (ANHYDROUS DEXTI /IQ8X) (SODIUM CATION - UNII:LYR4	hloride injecti Item Code (S	on, solu Source) Bas Stre DEXTRO: MONOHY SODIUM	sis of ength SE (DRATE DE	50 g in 1000 m
extrose monoh Product Infor Product Type Route of Admini Active Ingredi DEXTROSE MONO JNII:5SL0G7R00K) SODIUM CHLORID CHLORIDE ION - UNI POTASSIUM CHLO	ydrate, sodiu mation istration ient/Active Ing HYDRATE (UNII E (UNII: 451W47 I:Q32ZN48698) IRIDE (UNII: 660	m chloride, and potassium c HUMAN PRESCRIPTION DRUG INTRAVENOUS Moiety gredient Name : LX22YL083G) (ANHYDROUS DEXTI /IQ8X) (SODIUM CATION - UNII:LYR4	hloride injecti Item Code (S	Source) Bas Stree DEXTRO: MONOHY SODIUM CHLORIC POTASS	sis of ength SE (DRATE DE	Strengt 50 g in 1000 m 2.25 g in 1000 m 1.49 g
extrose monoh Product Infor Product Type Route of Admini Active Ingredi DEXTROSE MONO UNII:5SL0G7R00K) SODIUM CHLORID CHLORIDE ION - UNI POTASSIUM CHLORID INII:295053K152, C	ydrate, sodiu mation istration ient/Active light HYDRATE (UNII E (UNII: 451W47 I:Q32Z N48698) PRIDE (UNII: 660 HLORIDE ION -	m chloride, and potassium c HUMAN PRESCRIPTION DRUG INTRAVENOUS Moiety gredient Name : LX22YL083G) (ANHYDROUS DEXTI /IQ8X) (SODIUM CATION - UNII:LYR4	hloride injecti Item Code (S	Source) Bas Stree DEXTRO: MONOHY SODIUM CHLORIC POTASS	sis of ength SE (DRATE DE	Strengt 50 g in 1000 m 2.25 g in 1000 m 1.49 g
extrose monoh Product Infor Product Type Route of Admini Active Ingredi DEXTROSE MONO UNII:5SL0G7R00K) SODIUM CHLORID CHLORIDE ION - UNI POTASSIUM CHLORID INII:295053K152, C	ydrate, sodiu mation istration ient/Active light HYDRATE (UNII E (UNII: 451W47 I:Q32Z N48698) PRIDE (UNII: 660 HLORIDE ION -	m chloride, and potassium c HUMAN PRESCRIPTION DRUG INTRAVENOUS Moiety gredient Name : LX22YL083G) (ANHYDROUS DEXTI /IQ8X) (SODIUM CATION - UNII:LYR4	hloride injecti Item Code (S	Source) Bas Stree DEXTRO: MONOHY SODIUM CHLORIC POTASS	ition NDC is of ength SE (DRATE DE IUM DE	Strengt 50 g in 1000 m 2.25 g in 1000 m 1.49 g
extrose monoh Product Infor Product Type Route of Admini Active Ingredi DINII:5SLOG7ROOK) SODIUM CHLORID HILORIDE ION - UNI HILORIDE ION - UNI OTASSIUM CHLO INII:295053K152, C	ydrate, sodiu mation istration ient/Active ing HYDRATE (UNII E (UNII: 451W47 I:Q32Z N48698) RIDE (UNII: 660 CHLORIDE ION -	m chloride, and potassium c HUMAN PRESCRIPTION DRUG INTRAVENOUS Moiety gredient Name : LX22YL083G) (ANHYDROUS DEXT PIQ8X) (SODIUM CATION - UNII:LYR4 DYQ98I10) (POTASSIUM CATION - UNII:Q32Z N48698)	hloride injecti Item Code (S	Source) Bas Stree DEXTRO: MONOHY SODIUM CHLORIC POTASS	ition NDC is of ength SE (DRATE DE IUM DE	Strengt 50 g in 1000 m 2.25 g in 1000 m 1.49 g in 1000 m
extrose monoh Product Infor Product Type Route of Admini Active Ingredi DINII:5SL0G7R00K) SODIUM CHLORID HLORIDE ION - UNI COTASSIUM CHLORID INII:295053K152, C nactive Ingre	ydrate, sodiu mation istration istration ient/Active Ing HYDRATE (UNII E (UNII: 451W47 I:Q32ZN48698) RIDE (UNII: 660 CHLORIDE ION -	m chloride, and potassium c HUMAN PRESCRIPTION DRUG INTRAVENOUS Moiety gredient Name : LX22YL083G) (ANHYDROUS DEXTI 7(Q8X) (SODIUM CATION - UNII:LYR4 (YQ98I10) (POTASSIUM CATION - UNII:Q32Z N48698)	hloride injecti Item Code (S	Source) Bas Stree DEXTRO: MONOHY SODIUM CHLORIC POTASS	ition NDC is of ength SE (DRATE DE IUM DE	Strengt Strengt 50 g in 1000 m 2.25 g in 1000 m 1.49 g in 1000 m
extrose monoh Product Infor Product Type Route of Admini Active Ingredi DEXTROSE MONO JNII:5SL0G7ROOK) SODIUM CHLORIDE CHLORIDE ION - UNI COTASSIUM CHLORIDE UNII:295053K152, CO Inactive Ingredi WATER (UNII: 059Q	ydrate, sodiu mation istration istration ient/Active Ing HYDRATE (UNII E (UNII: 451W47 I:Q32ZN48698) RIDE (UNII: 660 CHLORIDE ION -	m chloride, and potassium c HUMAN PRESCRIPTION DRUG INTRAVENOUS Moiety gredient Name : LX22YL083G) (ANHYDROUS DEXTI 7(Q8X) (SODIUM CATION - UNII:LYR4 (YQ98I10) (POTASSIUM CATION - UNII:Q32Z N48698)	hloride injecti Item Code (S	Source) Bas Stree DEXTRO: MONOHY SODIUM CHLORIC POTASS	ition NDC is of ength SE (DRATE DE IUM DE	Strengt 50 g in 1000 m 2.25 g in 1000 m 1.49 g in 1000 m
extrose monoh Product Infor Product Type Route of Admini Active Ingredi DEXTROSE MONO UNII:5SLOG7ROOK) SODIUM CHLORID CHLORIDE ION - UNI POTASSIUM CHLORID CHLORIDE ION - UNI POTASSIUM CHLORID INII:295053K152, C MACTER (UNII: 059Q HYDROCHLORIC A	ydrate, sodiu mation istration istration ient/Active Ing HYDRATE (UNII E (UNII: 451W47 I:Q32ZN48698) RIDE (UNII: 660 CHLORIDE ION -	m chloride, and potassium c HUMAN PRESCRIPTION DRUG INTRAVENOUS Moiety gredient Name : LX22YL083G) (ANHYDROUS DEXTI 7(Q8X) (SODIUM CATION - UNII:LYR4 (YQ98I10) (POTASSIUM CATION - UNII:Q32Z N48698)	hloride injecti Item Code (S	Source) Bas Stree DEXTRO: MONOHY SODIUM CHLORIC POTASS	ition NDC is of ength SE (DRATE DE IUM DE	Strengt Strengt 50 g in 1000 m 2.25 g in 1000 m 1.49 g in 1000 m
extrose monohi Product Infor Product Type Route of Admini Active Ingredi DEXTROSE MONO INII:5SL0G7R0OK) SODIUM CHLORID CHLORIDE ION - UNI POTASSIUM CHLORID INII:295053K152, C NATER (UNII: 059Q HYDROCHLORIC A Packaging	ydrate, sodiu mation istration ient/Active light HYDRATE (UNII E (UNII: 451W47 I:Q32ZN48698) RIDE (UNII: 451W47 I:Q32ZN48698) RIDE (UNII: 660 CHLORIDE ION - edients	m chloride, and potassium c HUMAN PRESCRIPTION DRUG INTRAVENOUS Moiety gredient Name : LX22YL083G) (ANHYDROUS DEXTI 7(Q8X) (SODIUM CATION - UNII:LYR4 (YQ98I10) (POTASSIUM CATION - UNII:Q32Z N48698)	hloride injecti Item Code (S ROSE - MONH37, Marketing	Source) Bas Stre DEXTRO: MONOHY SODIUM CHLORID POTASS CHLORID	ition NDC	Strengt 50 g in 1000 n 2.25 g in 1000 n 1.49 g in 1000 n
extrose monohi Product Infor Product Type Route of Admini Active Ingredi DEXTROSE MONO JNII:5SL0G7R0OK) SODIUM CHLORID CHLORIDE ION - UNI POTASSIUM CHLORID INII:295053K152, C NATER (UNII: 059Q HYDROCHLORIC A Packaging # Item Code NDC:0000, 7001	ydrate, sodiu mation istration ient/Active Ing HYDRATE (UNII E (UNII: 451W47 I:Q32ZN48698) RIDE (UNII: 451W47 I:Q32ZN48698) RIDE (UNII: 660 CHLORIDE ION - edients FOKOOR) CID (UNII: QTT1	m chloride, and potassium c HUMAN PRESCRIPTION DRUG INTRAVENOUS Moiety gredient Name : LX22YL083G) (ANHYDROUS DEXT (Q8X) (SODIUM CATION - UNII:LYRA (SODIUM CATION - UNII:LYRA	hloride injecti Item Code (S ROSE - MONH37, Marketing Date	Source) Bas Stre DEXTRO: MONOHY SODIUM CHLORID POTASS CHLORID	ition NDC	Strengt Strengt S0 g in 1000 n 2.25 g in 1000 n 1.49 g in 1000 n
Product Infor Product Type Route of Admini Active Ingredi DEXTROSE MONO UNII:5SL0G7R00K) SODIUM CHLORID CHLORIDE ION - UNI POTASSIUM CHLORID UNII:295053K152, C Inactive Ingre WATER (UNII: 059Q HYDROCHLORIC A Packaging # Item Code	ydrate, sodiu mation istration ient/Active light HYDRATE (UNII E (UNII: 451W47 I:Q32ZN48698) RIDE (UNII: 451W47 I:Q32ZN48698) RIDE (UNII: 660 CHLORIDE ION - edients	m chloride, and potassium c HUMAN PRESCRIPTION DRUG INTRAVENOUS Moiety gredient Name : LX22YL083G) (ANHYDROUS DEXT (Q8X) (SODIUM CATION - UNII:LYRA (SODIUM CATION - UNII:LYRA	hloride injecti Item Code (S ROSE - MONH37, Marketing	Source) Bas Stre DEXTRO: MONOHY SODIUM CHLORID POTASS CHLORID	ition NDC	Strengt 50 g in 1000 m 2.25 g in 1000 m 1.49 g in 1000 m

 1
 1 in 1 POUCH

 1
 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

POTASSIUM CHLORIDE IN DEXTROSE AND SODIUM CHLORIDE

dextrose monohydrate, sodium chloride, and potassium chloride injection, solution

Product Information Product Type HUMAN PRESCRIPTION DRUG Item Code (Source) NDC:0990-7902				

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:55L0G7R00K)	DEXTROSE MONOHYDRATE	50 g in 1000 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	4.5 g in 1000 mL
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295053K152, CHLORIDE ION - UNII:Q32ZN48698)	POTASSIUM CHLORIDE	1.49 g in 1000 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging		

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:0990-7902- 03	24 in 1 CASE	02/01/2020	
1		1 in 1 POUCH		
1		500 mL in 1 BAG; Type 0: Not a Combination Product		
2	NDC:0990-7902- 09	12 in 1 CASE	02/01/2020	
2		1 in 1 POUCH		
2		1000 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
NDA	NDA018362	02/01/2020	

Labeler - ICU Medical Inc. (118380146)

Revised: 10/2021

ICU Medical Inc.