POTASSIUM CHLORIDE- potassium chloride injection, solution
ICU Medical Inc.

POTASSIUM CHLORIDE INJECTION

For Use Only With A Calibrated Infusion Device

Highly Concentrated

Flexible Plastic Container

Ready To Use

R_x only

DESCRIPTION

This Potassium Chloride Injection is a sterile, nonpyrogenic, highly concentrated, ready-to-use solution of Potassium Chloride, USP in Water for Injection, USP for electrolyte replenishment in a single dose container for intravenous administration. It contains no antimicrobial agents.

Potassium Chloride Injection mEq Potassium/ Container	**Composition** (g/L) Potassium Chloride, USP (KCl)	**Osmolarity* (mOsmol/L) (calc)**	**pH**	**Ionic Concentration** (mEq/L)	
				Potassium	Chloride
10 mEq/100 mL	7.45	**200**	5.8 (4.0 to 8.0)	**100**	100
10 mEq/50 mL 20 mEq/100 mL	14.9	**400**	5.8 (4.0 to 8.0)	**200**	200
20 mEq/50 mL 40 mEq/100 mL	29.8	**799**	5.8 (4.0 to 8.0)	**400**	400

*Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L. Administration of substantially hypertonic solutions (≥600 mOsmol/L) may cause vein damage.

This flexible plastic container is fabricated from a specially formulated polyvinylchloride. 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. The amount of water that can permeate from inside the container into the overwrap is insufficient to affect the solution significantly. Solutions in contact with the plastic container may leach out certain of its chemical components from the plastic in very small amounts; however, biological testing was supportive of the safety of the plastic container

materials.

CLINICAL PHARMACOLOGY

Potassium is the major cation of body cells (160 mEq/liter of intracellular water) and is concerned with the maintenance of body fluid composition and electrolyte balance. Potassium participates in carbohydrate utilization, protein synthesis, and is critical in the regulation of nerve conduction and muscle contraction, particularly in the heart. Chloride, the major extracellular anion, closely follows the metabolism of sodium, and changes in the acid-base of the body are reflected by changes in the chloride concentration.

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.

INDICATIONS AND USAGE

Potassium Chloride Injection is indicated in the treatment of potassium deficiency states when oral replacement is not feasible.

THIS HIGHLY CONCENTRATED, READY-TO-USE POTASSIUM CHLORIDE INJECTION IS INTENDED FOR THE MAINTENANCE OF SERUM K^+ LEVELS AND FOR POTASSIUM SUPPLEMENTATION IN FLUID RESTRICTED PATIENTS WHO CANNOT ACCOMMODATE ADDITIONAL VOLUMES OF FLUID ASSOCIATED WITH POTASSIUM SOLUTIONS OF LOWER CONCENTRATION.

When using these products, these patients should be on continuous cardiac monitoring and frequent testing for serum potassium concentration and acid-base balance.

CONTRAINDICATIONS

Potassium Chloride Injection is contraindicated in diseases where high potassium levels may be encountered, and in patients with hyperkalemia, renal failure and in conditions in which potassium retention is present.

WARNINGS

THIS HIGHLY CONCENTRATED, READY-TO-USE POTASSIUM CHLORIDE INJECTION IS INTENDED FOR THE MAINTENANCE OF SERUM K^+ LEVELS AND FOR POTASSIUM SUPPLEMENTATION IN FLUID RESTRICTED PATIENTS WHO CANNOT ACCOMMODATE ADDITIONAL VOLUMES OF FLUID ASSOCIATED WITH POTASSIUM SOLUTIONS OF LOWER CONCENTRATION.

TO AVOID POTASSIUM INTOXICATION, DO NOT INFUSE THESE SOLUTIONS RAPIDLY.

PATIENTS REQUIRING HIGHLY CONCENTRATED SOLUTIONS SHOULD BE KEPT ON CONTINUOUS CARDIAC MONITORING AND UNDERGO FREQUENT TESTING FOR SERUM POTASSIUM AND ACID-BASE BALANCE, ESPECIALLY IF THEY RECEIVE DIGITALIS.

In patients with renal insufficiency, administration of potassium chloride may cause potassium intoxication and life-threatening hyperkalemia.

Administer intravenously only with a calibrated infusion device at a slow, controlled rate. (See ***DOSAGE AND ADMINISTRATION*****.) Because pain associated with peripheral infusion of**

Potassium Chloride solution has been reported, whenever possible administration via a central route is recommended for thorough dilution by the blood stream and avoidance of extravasation. Highest concentrations (300 and 400 mEq/L) should be exclusively administered via central route.

The administration of intravenous solutions can cause fluid and/or solute overload 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. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentration.

PRECAUTIONS

Laboratory Tests

Serum potassium levels are not necessarily indicative of tissue potassium levels. Solutions containing potassium should be used with caution in the presence of cardiac or renal disease.

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. Significant deviations from normal concentrations may require the use of additional electrolyte supplements, or the use of electrolyte-free dextrose solutions to which individualized electrolyte supplements may be added.

Pregnancy:

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

Pediatric Use:

These products should not be used in pediatric patients at this time.

Do not administer unless solution is clear and seal is intact.

ADVERSE REACTIONS

Potassium intoxication with mild or severe hyperkalemia has been reported. The signs and symptoms of intoxication include paresthesia of the extremities, areflexia, muscular or respiratory paralysis, mental confusion, weakness, hypotension, cardiac arrhythmia, heart block, electrographic abnormalities and cardiac arrest. EKG abnormalities serve as a clinical reflection of the seriousness of changes in serum potassium concentrations: peaked T waves and prolonged P-R intervals usually occur with modest elevations above the upper limit of normal potassium concentrations; P waves disappear, the QRS complex widens, and eventual asystole usually occurs with higher elevations.

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.

Infusion of highly concentrated potassium chloride solutions may cause local pain and vein irritation. (See ***WARNINGS***).

Reactions reported with the use of potassium-containing solutions include nausea, vomiting, and abdominal pain and diarrhea.

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 hyperkalemia, discontinue the infusion immediately and institute corrective therapy to reduce serum potassium levels as necessary. The use of potassium containing foods or medications must also be eliminated.

Treatment of mild to severe hyperkalemia with signs and symptoms of potassium intoxication includes the following:

1. Dextrose Injection, USP, 10% or 25%, containing 10 units of crystalline insulin per 20 grams of dextrose administered intravenously, 300 to 500 mL per hour.
2. Absorption and exchange of potassium using sodium or ammonium cycle cation exchange resin, orally and as retention enema.
3. Hemodialysis and peritoneal dialysis.

In cases of digitalization, too rapid a lowering of plasma potassium concentration can cause digitalis toxicity.

DOSAGE AND ADMINISTRATION

The dose and rate of administration are dependent upon the specific condition of each patient.

Administer intravenously only with a calibrated infusion device at a slow, controlled rate. Because pain associated with peripheral infusion of Potassium Chloride solution has been reported, whenever possible, administration via central route is recommended for thorough dilution by the blood stream and avoidance of extravasation. Highest concentrations (300 and 400 mEq/L) should be exclusively administered via central route.

Recommended administration rates should not usually exceed 10 mEq/hour or 200 mEq for a 24-hour period if the serum potassium level is greater than 2.5 mEq/liter.

In urgent cases where the serum potassium level is less than 2 mEq/liter or where severe hypokalemia is a threat (serum potassium level less than 2 mEq/liter and electrocardiographic changes and/or muscle paralysis), rates up to 40 mEq/hour or 400 mEq over a 24-hour period can be administered very carefully when guided by continuous monitoring of the EKG and frequent serum K^+ determinations to avoid hyperkalemia and cardiac arrest.

Parenteral drug products should be inspected visually for particulate matter and discoloration, whenever solution and container permit. Use of a final filter is recommended during administration of all parenteral solutions where possible.

Do not add supplementary medication.

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. Do not add supplementary medication. Such use could result in air embolism due to residual air being drawn from the primary container before administration of the fluid from the secondary container is completed.

HOW SUPPLIED

Potassium Chloride Injection in flexible plastic containers is available as follows:

NDC No.	Potassium per container
0409–7074–26	10 mEq/100 mL
0990-7074-26	10 mEq/100 mL
0409–7075–14	10 mEq/50 mL
0990-7075-14	10 mEq/50 mL
0409–7075–26	20 mEq/100 mL
0990-7075-26	20 mEq/100 mL
0409–7077–14	20 mEq/50 mL
0990-7077-14	20 mEq/50 mL
0409–7077–26	40 mEq/100 mL
0990-7077-26	40 mEq/100 mL

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

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

Revised: June, 2018	EN-4654

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

PRINCIPAL DISPLAY PANEL - 100 mL Bag Label

For Use Only With A Calibrated Infusion Device

Highly Concentrated
100 mEq/L

100 mL
NDC 0990-7074-26

POTASSIUM CHLORIDE Inj.

10
mEq

EACH 100 mL CONTAINS POTASSIUM CHLORIDE
745 mg IN WATER FOR INJECTION. ELECTROLYTES
PER 1000 mL: POTASSIUM 100 mEq; CHLORIDE
100 mEq.
200 mOsmol/LITER (CALC.)
pH 5.8 (4.0 to 8.0)

DO NOT ADD SUPPLEMENTARY MEDICATION.
WHENEVER POSSIBLE USE CENTRAL ROUTE.

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.

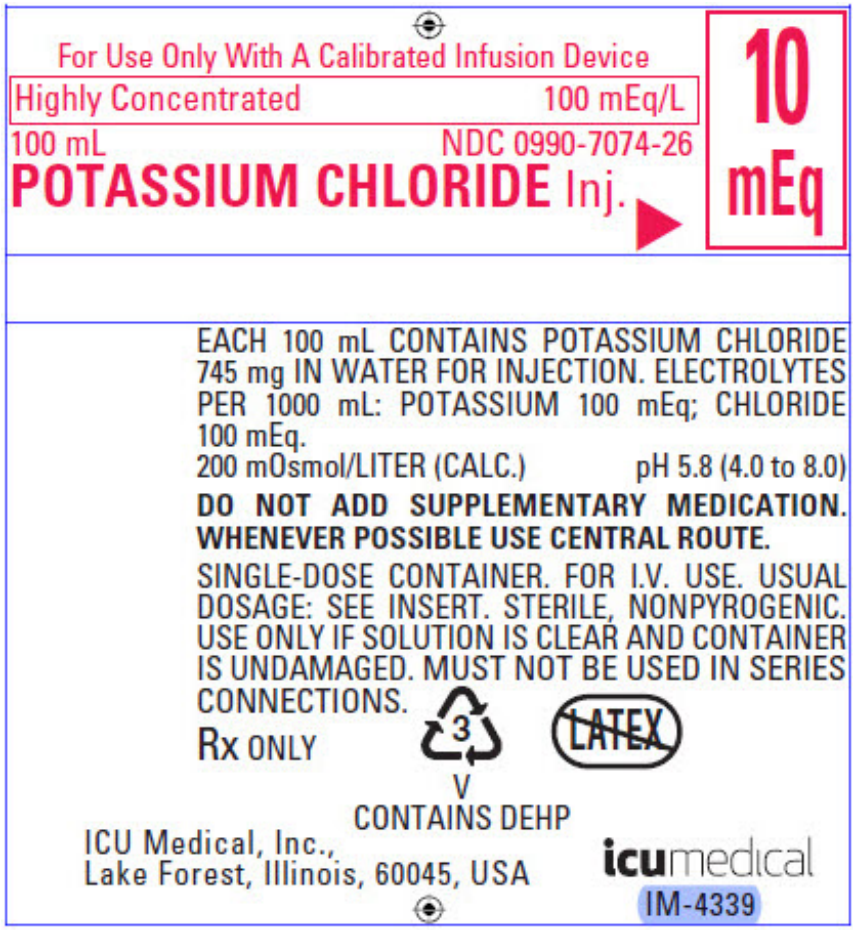
Rx ONLY

3
V
CONTAINS DEHP

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

icumedical

IM-4339



PRINCIPAL DISPLAY PANEL - 100 mL Bag Pouch Label

TO OPEN – TEAR AT NOTCH
NDC 0990-7074-26
For use only with a calibrated infusion device.
HIGHLY CONCENTRATED

100
mEq/L

POTASSIUM
CHLORIDE Inj.

10
mEq

Total in 100 mL

Each 100 mL contains potassium chloride 745 mg in water for injection.
Electrolytes per 1000 mL: potassium 100 mEq; chloride 100 mEq.
200 mOsmol/liter (CALC.)
pH 5.8 (4.0 to 8.0)

DO NOT ADD SUPPLEMENTARY MEDICATION. WHENEVER POSSIBLE USE CENTRAL ROUTE.

Single-dose container. For I.V. use. Usual dosage: See insert. Sterile, nonpyrogenic. Use only if solution is clear. After removing the overwrap, check for minute leaks by squeezing container firmly. If leaks are found, discard unit as sterility may be impaired. Must not be used in series connections.

The overwrap is a moisture barrier. Do not remove unit from overwrap until ready for use. Use unit promptly when pouch is opened. Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.] Protect from freezing. See insert.

Rx only

7
OTHER

F WR-0529

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

icumedical

PRINCIPAL DISPLAY PANEL - 50 mL Bag Label - IM-4340

For Use Only With A Calibrated Infusion Device

Highly Concentrated
200 mEq/L

50 mL
NDC 0990-7075-14

POTASSIUM CHLORIDE Inj.

10
mEq

EACH 100 mL CONTAINS POTASSIUM CHLORIDE 1490 mg IN WATER FOR INJECTION. ELECTROLYTES PER 1000 mL: POTASSIUM 200 mEq; CHLORIDE 200 mEq.
400 mOsmol/LITER (CALC.)
pH 5.8 (4.0 to 8.0)

DO NOT ADD SUPPLEMENTARY MEDICATION. WHENEVER POSSIBLE USE CENTRAL ROUTE.

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

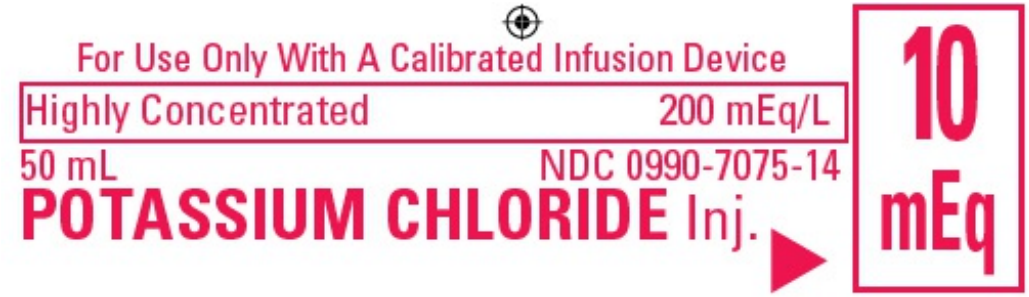
Rx ONLY

3
V
CONTAINS DEHP

icumedical

IM-4340

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



PRINCIPAL DISPLAY PANEL - 50 mL Bag Pouch Label - WR-0530

TO OPEN – TEAR AT NOTCH
NDC 0990-7075-14
For use only with a calibrated infusion device.
HIGHLY CONCENTRATED

200
mEq/L

POTASSIUM
CHLORIDE Inj.

10
mEq

Total in 50 mL

Each 100 mL contains potassium chloride 1490 mg in water for injection.
Electrolytes per 1000 mL: potassium 200 mEq; chloride 200 mEq.
400 mOsmol/liter (CALC.)
pH 5.8 (4.0 to 8.0)

DO NOT ADD SUPPLEMENTARY MEDICATION. WHENEVER POSSIBLE USE CENTRAL ROUTE.

Single-dose container. For I.V. use. Usual dosage: See insert. Sterile, nonpyrogenic. Use only if solution is clear. After removing the overwrap, check for minute leaks by squeezing container firmly. If leaks are found, discard unit as sterility may be impaired. Must not be used in series connections.

The overwrap is a moisture barrier. Do not remove unit from overwrap until ready for use. Use unit promptly when pouch is opened. Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.] Protect from freezing. See insert.

Rx only

7
OTHER

F WR-0530

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

icumedical

PRINCIPAL DISPLAY PANEL - 50 mL Bag Label - IM-4342

For Use Only With A Calibrated Infusion Device

Highly Concentrated
400 mEq/L

50 mL
NDC 0990-7077-14

POTASSIUM CHLORIDE Inj.

20
mEq

EACH 50 mL CONTAINS POTASSIUM CHLORIDE
1.49 g IN WATER FOR INJECTION. ELECTROLYTES
PER 1000 mL: POTASSIUM 400 mEq; CHLORIDE
400 mEq.
799 mOsmol/LITER (CALC.)
pH 5.8 (4.0 to 8.0)
HYPERTONIC – MAY CAUSE VEIN DAMAGE.
DO NOT ADD SUPPLEMENTARY MEDICATION.
WHENEVER POSSIBLE USE CENTRAL ROUTE.
DISCONTINUE INFUSION IF ADVERSE REACTION
OCCURS. 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-4342

icumedical

PRINCIPAL DISPLAY PANEL - 50 mL Bag Pouch Label - WR-0536

TO OPEN – TEAR AT NOTCH
NDC 0990-7077-14
For use only with a calibrated infusion device.
HIGHLY CONCENTRATED

20

mEq

POTASSIUM
CHLORIDE Inj.

400
mEq/L

Total in 50 mL

Each 50 mL contains potassium chloride 1.49 g in water for injection. Electrolytes per 1000 mL: potassium 400 mEq; chloride 400 mEq.
799 mOsmol/liter (CALC.)
pH 5.8 (4.0 to 8.0)
Hypertonic – may cause vein damage.

DO NOT ADD SUPPLEMENTARY MEDICATION. WHENEVER POSSIBLE USE CENTRAL ROUTE.

Discontinue infusion if adverse reaction occurs.

Single-dose container. For I.V. use. Usual dosage: See insert. Sterile, nonpyrogenic. Use only if solution is clear. After removing the overwrap, check for minute leaks by squeezing container firmly. If leaks are found, discard unit as sterility may be impaired. Must not be used in series connections.

The overwrap is a moisture barrier. Do not remove unit from overwrap until ready for use. Use unit promptly when pouch is opened. Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.] Protect from freezing. See insert.

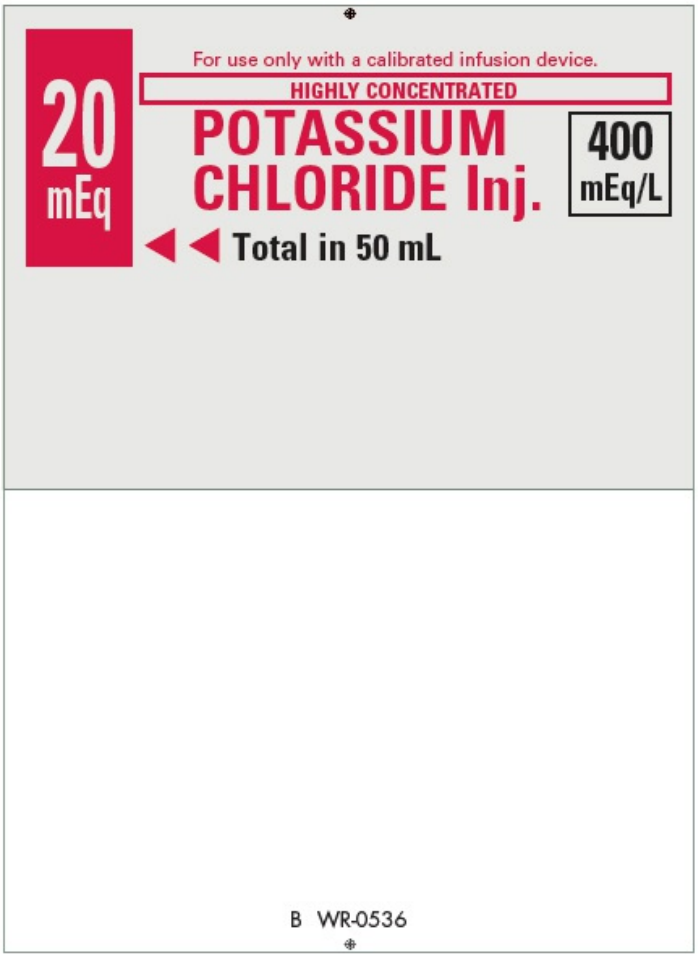
Rx only

7
OTHER

F WR-0536

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

icumedical



POTASSIUM CHLORIDE

potassium chloride injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0990-7074
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152, CHLORIDE ION - UNII:Q32ZN48698)	POTASSIUM CHLORIDE	10 meq in 100 mL

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

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**

1	NDC:0990-7074-26	24 in 1 CASE	05/01/2019	
1		1 in 1 POUCH		
1		100 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	NDA020161	04/01/2019	

POTASSIUM CHLORIDE

potassium chloride injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0990-7075
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152, CHLORIDE ION - UNII:Q32ZN48698)	POTASSIUM CHLORIDE	200 meq in 1000 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0990-7075-14	24 in 1 CASE	04/01/2019	
1		1 in 1 POUCH		
1		50 mL in 1 BAG; Type 0: Not a Combination Product		
2	NDC:0990-7075-26	24 in 1 CASE	04/01/2019	
2		1 in 1 POUCH		
2		100 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	NDA020161	04/01/2019	

POTASSIUM CHLORIDE

potassium chloride injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0990-7077
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152, CHLORIDE ION - UNII:Q32ZN48698)	POTASSIUM CHLORIDE	400 meq in 1000 mL

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0990-7077-14	24 in 1 CASE	06/01/2019	
1		1 in 1 POUCH		
1		50 mL in 1 BAG; Type 0: Not a Combination Product		
2	NDC:0990-7077-26	24 in 1 CASE	12/31/2019	
2		1 in 1 POUCH		
2		100 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	NDA020161	04/01/2019	

Labeler - ICU Medical Inc. (118380146)

Revised: 2/2019 ICU Medical Inc.