POTASSIUM CHLORIDE - potassium chloride injection
Fresenius Kabi USA, LLC

For Use Only with a Calibrated Infusion Device

freeflex®

Highly Concentrated

Potassium Chloride Injection
in Plastic Container Ready
To Use

free*flex*® Container

Rx 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.

	Composition (g/L)	**Osmolarity* (mOsmol/L) (calc)**	**pH**	**Ionic Concentration** (mEq/L)	
Potassium Chloride Injection mEq Potassium/Container	Potassium Chloride, USP (KCl)			**Potassium**	Chloride
10 mEq/100 mL	7.46	**200**	5.0 (4.0 to 8.0)	**100**	100
10 mEq/50 mL 20 mEq/100 mL	14.9	**400**	5.0 (4.0 to 8.0)	**200**	200
20 mEq/50 mL 40 mEq/100 mL	29.8	**799**	5.0 (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.

The flexible plastic container is fabricated from a specially formulated non-plasticized, film containing polypropylene and thermoplastic elastomers (**free***flex*® bag). 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 flexible container can leach out certain of the container's chemical components in very small amounts within the expiration period.

The suitability of the container material has been confirmed by tests in animals according to USP biological tests for plastic containers.

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 patients with:

- hyperkalemia
- known hypersensitivity to Potassium Chloride Injection

WARNINGS

Hyperkalemia

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.

Potassium Chloride Injection should be administered with extreme caution, if at all, to patients with conditions predisposing to hyperkalemia and/or associated with increased sensitivity to potassium, such as patients with:

- severe renal impairment
- acute dehydration
- extensive tissue injury or burns
- certain cardiac disorders such as congestive heart failure or AV block
- potassium-aggravated skeletal muscle channelopathies (e.g., hyperkalemic periodic paralysis, paramyotonia congenita, and potassium-aggravated myotonia/paramyotonia).

Potassium Chloride Injection should be administered with caution to patients who are at risk of experiencing hyperosmolality, acidosis, or undergo correction of alkalosis (conditions associated with a shift of potassium from intracellular to extracellular space) and patients treated concurrently or recently with agents or products that can cause hyperkalemia (see **PRECAUTIONS, Drug Interactions).**

If used in high-risk patients, especially close monitoring and careful dose selection and adjustment is required.

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.

Administration of concentrated potassium solutions can cause cardiac conduction disorders (including complete heart block) and other cardiac arrhythmias at any time during infusion. Continuous cardiac monitoring is performed to aid in the detection of cardiac arrhythmias due to a sudden increase in serum potassium concentration (e.g., when potassium infusion is started), or transient or sustained hyperkalemia (see **ADVERSE REACTIONS** and **OVERDOSAGE).**

Frequently, mild or moderate hyperkalemia is asymptomatic and may be manifested only by increased serum potassium concentrations and, possibly, characteristic EKG changes. However, fatal arrhythmias can develop at any time during hyperkalemia.

Serum potassium levels are not necessarily indicative of tissue potassium levels.

Tissue Damage and Thrombophlebitis

When infusing concentrated potassium solutions, including Potassium Chloride Injection, care must be taken to prevent paravenous administration or extravasation because such solutions may be associated with tissue damage, which may be severe and include vascular, nerve, and tendon damage, leading to surgical intervention, including amputation. Secondary complications including pulmonary embolism from thrombophlebitis have been reported as a consequence of tissue damage from

potassium chloride.

Administer intravenously only with a calibrated infusion device at a slow, controlled rate. (see **DOSAGE AND ADMINISTRATION). Highest concentrations (400 mEq per L) should be exclusively administered via central intravenous route.**

Whenever possible, administration via a central route is recommended for all concentrations of Potassium Chloride Injection for thorough dilution by the blood stream and decreasing the risk of extravasation and to avoid pain and phlebitis associated with peripheral infusion. Correct placement of the catheter should be verified before administration.

Hyponatremia

Monitoring of serum sodium is particularly important for hypotonic fluids. Potassium Chloride Injection has an osmolarity of 200 to 799 mOsmol/L (see **DESCRIPTION**).

Potassium Chloride Injection may cause hyponatremia. The risk for hyponatremia is increased, in pediatric patients, elderly patients, postoperative patients, those with psychogenic polydipsia and in patients treated with medications that increase the risk of hyponatremia (such as certain diuretic, antiepileptic and psychotropic medications) (see **PRECAUTIONS, Drug Interactions**).

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

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

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

Fluid Overload

Depending on the volume and rate of infusion, and the patient's underlying clinical condition, the intravenous administration of Potassium Chloride Injection can cause electrolyte disturbances such as overhydration/hypervolemia and congested states including central (e.g., pulmonary edema) and peripheral edema.

Avoid Potassium Chloride Injection in patients with or at risk for fluid and/or solute overloading. If use cannot be avoided, monitor fluid balance, electrolyte concentrations and acid-base balance as needed and especially during prolonged use.

Hyperchloremia

In patients with or at risk of hyperchloremia, Potassium Chloride Injection may exacerbate or result in hyperchloremia. Monitor plasma chloride levels and renal function in such patients.

PRECAUTIONS

General

Do not connect flexible plastic containers in series in order to avoid air embolism due to possible residual air contained in the primary container.

Laboratory Tests

Serum potassium levels are not necessarily indicative of tissue potassium levels.

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.

Drug Interactions

Other Products that Cause Hyperkalemia

Administration of Potassium Chloride Injection in patients treated concurrently or recently with other products that can cause hyperkalemia or increase the risk of hyperkalemia, (e.g., potassium- sparing diuretics, ACE inhibitors, angiotensin II receptor antagonists, cyclosporine and tacrolimus) increases the risk of severe and potentially fatal hyperkalemia, in particular in the presence of other risk factors for hyperkalemia (see **WARNINGS**). Avoid use of Potassium Chloride Injection in patients receiving such products. If use cannot be avoided, monitor serum potassium concentrations.

Other Drugs that Increase the Risk of Hyponatremia

Administration of Potassium Chloride Injection in patients treated concomitantly with drugs associated with hyponatremia may increase the risk of developing hyponatremia (see **WARNINGS**). Avoid use of Potassium Chloride Injection in patients receiving drugs that may increase the risk of hyponatremia, such as diuretics and antiepileptics. Drugs that increase the vasopressin effect reduce renal electrolyte free water excretion and may also increase the risk of hyponatremia following treatment with intravenous fluids.

If use cannot be avoided, monitor serum sodium concentrations.

Pregnancy

There are no adequate, well controlled studies with Potassium Chloride Injection in pregnant women and animal reproduction studies have not been conducted with this drug. Therefore, it is not known whether Potassium Chloride Injection can cause fetal harm when administered to a pregnant woman. Potassium Chloride Injection should be given during pregnancy only if potential benefit justifies the potential risk to the fetus.

Nursing Mothers

It is not known whether this drug is present in human milk. Because many drugs are present in human milk, caution should be exercised when Potassium Chloride Injection is administered to a nursing mother.

Pediatric Use

These products should not be used in children at this time. Safety and effectiveness of Potassium Chloride Injection in pediatric patients have not been established by adequate and well-controlled studies.

ADVERSE REACTIONS

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

Immune system disorders: Hypersensitivity, as manifested by rash and angioedema

Metabolism and nutrition disorders: Hyperkalemia, hyponatremia

Cardiac disorders: Cardiac arrest*, asystole*, ventricular fibrillation*, bradycardia *as a manifestation of rapid intravenous administration and/or of hyperkalemia

Respiratory, Thoracic, and Mediastinal Disorders: Dyspnea

General disorders and administration site conditions: Chest pain, infusion site thrombosis, infusion site phlebitis, infusion site erythema, infusion site swelling, infusion site pain, infusion site irritation, and/or a burning sensation.

Nervous System Disorders: Hyponatremic encephalopathy

The following adverse reactions were reported in association with extravasation: Skin necrosis, skin ulcer, soft tissue necrosis, muscle necrosis, nerve injury, tendon injury, and vascular injury.

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC at 1-800- 551-7176 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

OVERDOSAGE

Potassium overdose can cause potentially fatal hyperkalemia. Manifestations of hyperkalemia include:

- Disturbances in cardiac conduction and arrhythmias, including bradycardia, heart block, asystole, ventricular tachycardia, ventricular fibrillation
- Hypotension
- Muscle weakness up to and including muscular and respiratory paralysis, paresthesia
- Gastrointestinal symptoms (ileus, nausea, vomiting, abdominal pain)

Frequently, mild or moderate hyperkalemia is asymptomatic and may be manifested only by increased serum potassium concentrations and, possibly, characteristic electrocardiographic changes. However, fatal arrhythmias can develop at any time.

In addition to arrhythmias and conduction disorders, the EKG shows progressive changes that occur with increasing potassium levels. Possible changes include:

- Peaking of T waves,
- Loss of P waves, and
- QRS widening.

However, the correlation between potassium levels and EKG changes is not precise, and whether or at which potassium level certain EKG signs develop depends on factors such as patient sensitivity, the presence of other electrolyte disorders, and the rapidity of the development of hyperkalemia.

The presence of any EKG findings that are suspected to be caused by hyperkalemia should be considered a medical emergency.

In the event of hyperkalemia, discontinue the infusion immediately and institute close EKG, laboratory and other monitoring and, as necessary, 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. Highest concentrations (400 mEq/L) should be exclusively administered via central intravenous route.

Whenever possible, administration via a central route is recommended for all concentrations of Potassium Chloride Injection for thorough dilution by the blood stream and decreasing the risk of extravasation and to avoid pain and phlebitis associated with peripheral infusion (see **WARNINGS).** Correct placement of the catheter should be verified before administration.

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

In urgent cases where the serum potassium level is less than 2.0 mEq per liter or where severe hypokalemia is a threat, (serum potassium level less than 2.0 mEq per liter and electrocardiographic changes and/or muscle paralysis) rates up to 40 mEq per 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. Do not administer unless solution is clear and seal is intact. Use of a final filter is recommended during administration of all parenteral solutions where possible.

Do not add supplementary medication.

HOW SUPPLIED

Potassium Chloride Injection in **free***flex*® is available as follows:

Product Code	Unit of Use	Strength	Unit of Sale
129121	NDC 65219-012-00 one 100 mL fill in 100 mL **free***flex*® bag	10 mEq/100 mL	NDC 65219-012-01 Package of 50 **free***flex*® bags
129041	NDC 65219-004-00 one 50 mL fill in 100 mL **free***flex*® bag	10 mEq/50 mL	NDC 65219-004-01 Package of 60 **free***flex*® bags
129061	NDC 65219-006-00 one 100 mL fill in 100 mL **free***flex*® bag	20 mEq/100 mL	NDC 65219-006-01 Package of 50 **free***flex*® bags
129081	NDC 65219-008-50 one 50 mL fill in 100 mL **free***flex*® bag	20 mEq/50 mL	NDC 65219-008-51 Package of 60 **free***flex*® bags
129101	NDC 65219-010-00 one 100 mL fill in 100 mL **free***flex*® bag	40 mEq/100 mL	NDC 65219-010-01 Package of 50 **free***flex*® bags

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

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. The container closure is not made with natural rubber latex. Non-PVC, Non-DEHP, Sterile.

INSTRUCTIONS FOR USE:

Check flexible container solution composition, lot number, and expiry date.

Do not remove solution container from its overwrap until immediately before use. Use sterile equipment and aseptic technique.

See **PRECAUTIONS** for information on the avoidance of air embolism.

To Open

1. Turn solution container over so that the text is face down. Using the pre-cut corner tabs, peel open the overwrap and remove solution container.
2. Check the solution container for leaks by squeezing firmly. If leaks are found, or if the seal is not intact, discard the solution.
3. Do not use if the solution is cloudy or a precipitate is present.

Preparation for Administration

1. Immediately before inserting the infusion set, break off BLUE Infusion Port Cap with the arrow pointing away from container.
2. Use a non-vented infusion set or close the air-inlet on a vented set.

3. Close the roller clamp of the infusion set.
4. Hold the base of BLUE Infusion Port.
5. Insert spike through BLUE Infusion Port by rotating wrist slightly until the spike is inserted. **NOTE:**
   See full directions accompanying administration set.

WARNING: Do not use flexible container in series connections.

Manufactured for:

FRESENIUS KABI

Lake Zurich, IL 60047
Made in Norway
www.fresenius-kabi.com/us

451699B
Revised: September 2023
01-59-16-006B

Package Label - Principal Display Panel - Potassium Chloride 10 mEq 100 mL Bag Label

freeflex® NDC 65219-**012**-00 **100 mL**

Highly Concentrated (100 mEq/L)

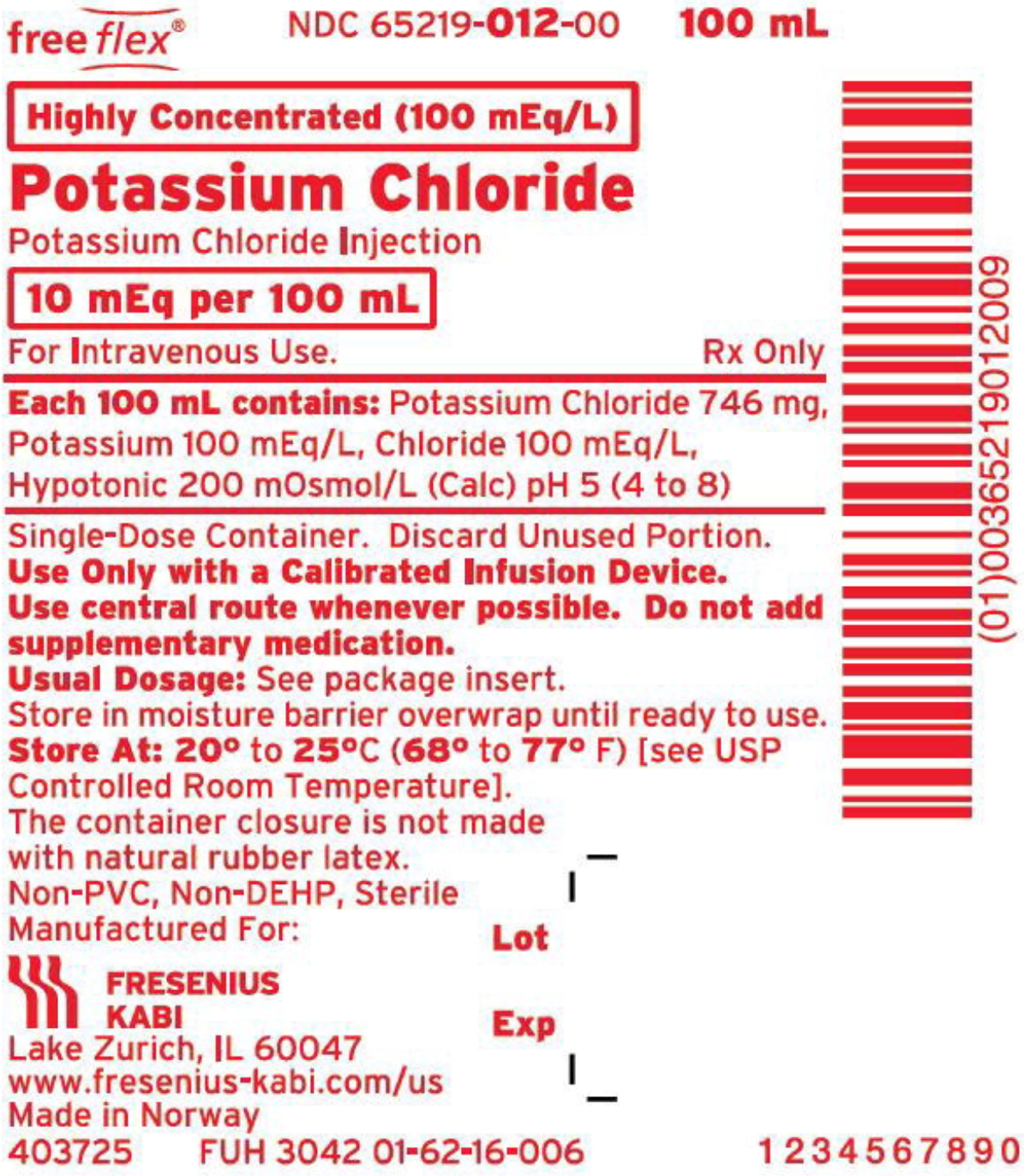
Potassium Chloride

Potassium Chloride Injection

10 mEq per 100 mL

For Intravenous Use.

Rx only



Package Label - Principal Display Panel - Potassium Chloride 10 mEq 50 mL Bag Label

freeflex® NDC 65219-**004**-00 **50 mL**

Highly Concentrated (200 mEq/L)

Potassium Chloride

Potassium Chloride Injection

10 mEq per 50 mL

For Intravenous Use.

Rx only

Package Label - Principal Display Panel - Potassium Chloride 20 mEq 100 mL Bag Label

freeflex® NDC 65219-**006**-00 **100 mL**

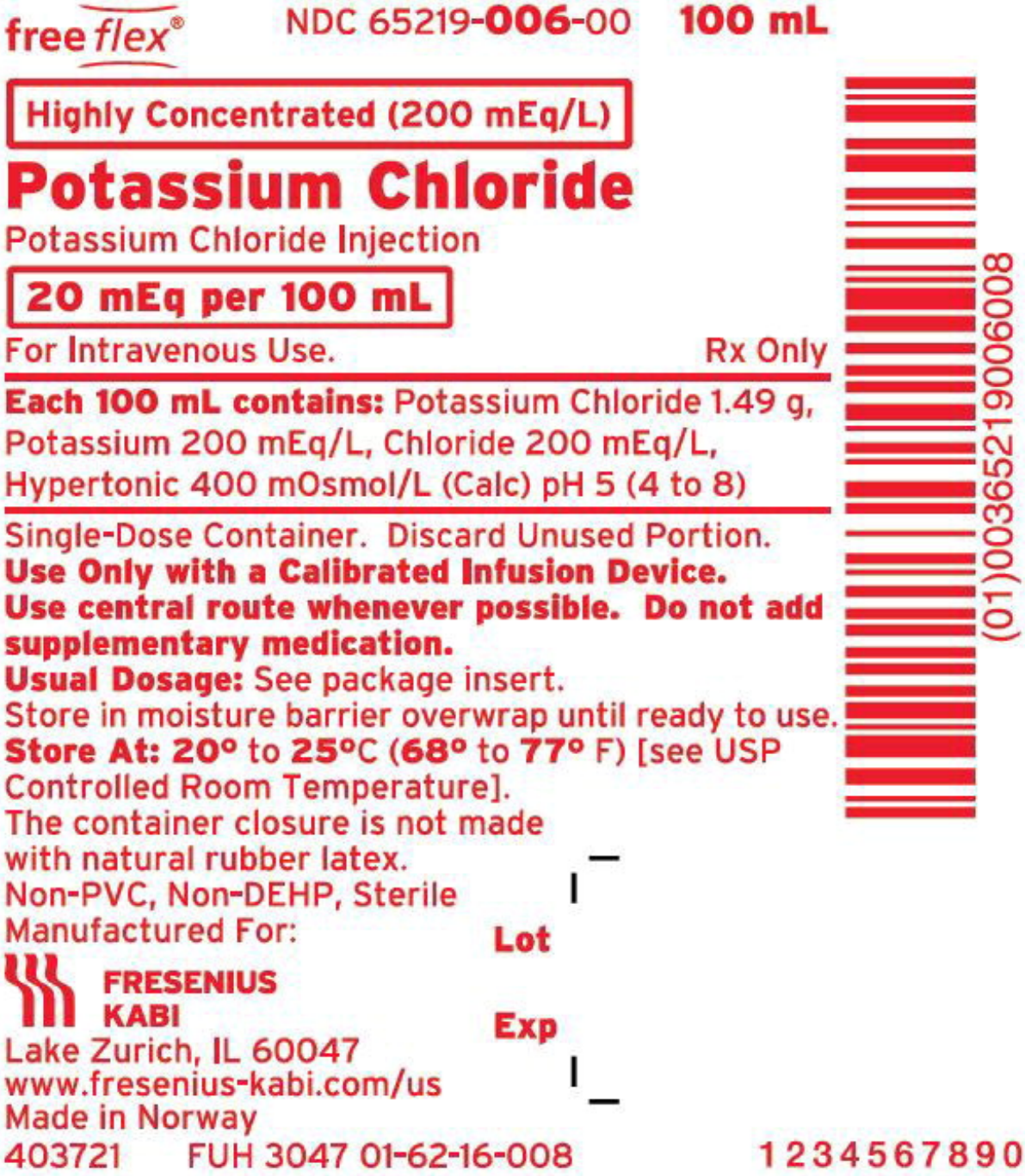
Highly Concentrated (200 mEq/L)

Potassium Chloride

Potassium Chloride Injection

20 mEq per 100 mL

For Intravenous Use. Rx Only



Package Label - Principal Display Panel - Potassium Chloride 20 mEq 50 mL Bag Label

freeflex® NDC 65219-**008**-50 **50 mL**

Highly Concentrated (400 mEq/L)

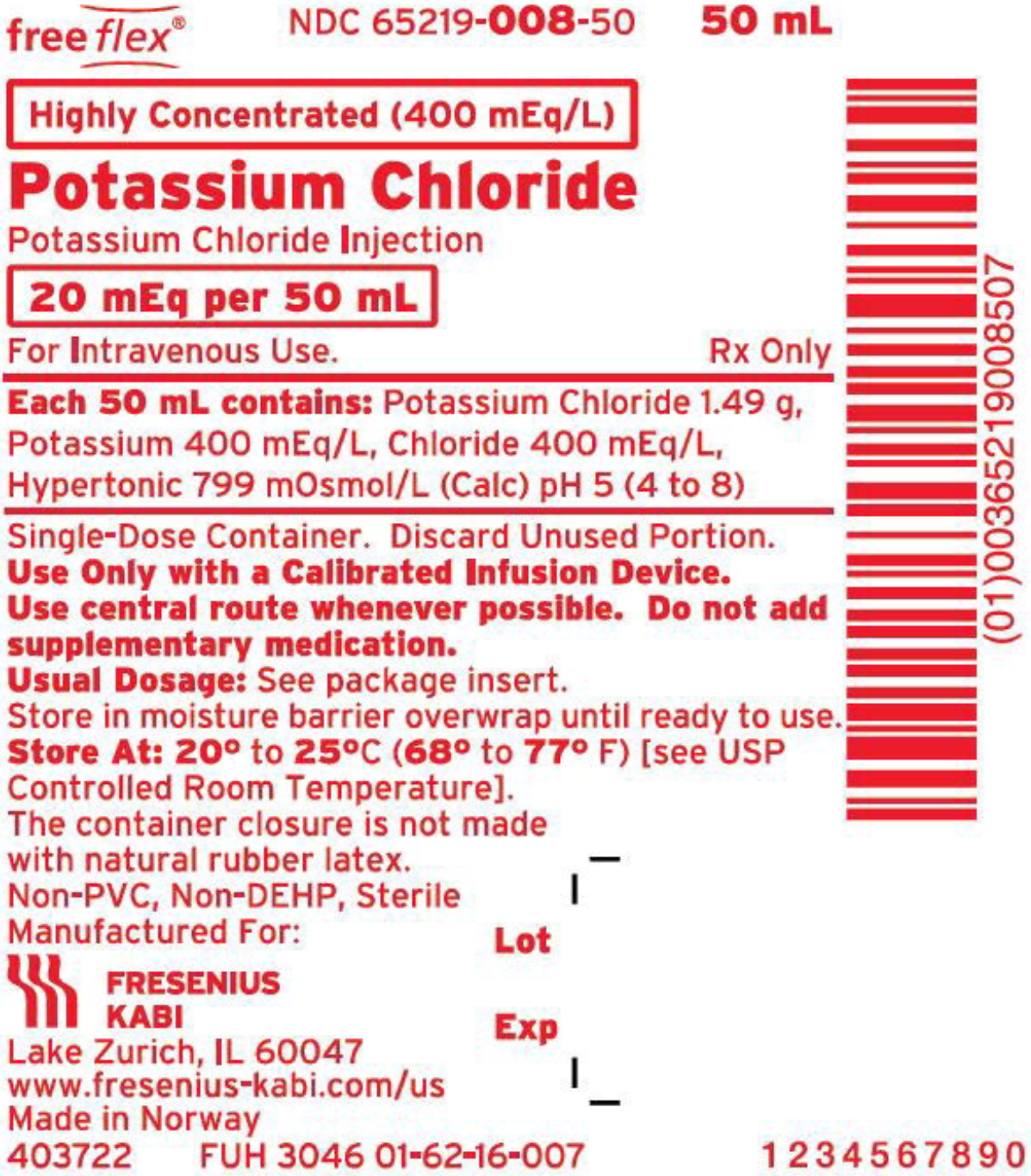
Potassium Chloride

Potassium Chloride Injection

20 mEq per 50 mL

For Intravenous Use.

Rx only



Package Label - Principal Display Panel - Potassium Chloride 40 mEq 100 mL Bag Label

freeflex® NDC 65219-**010**-00 **100 mL**

Highly Concentrated (400 mEq/L)

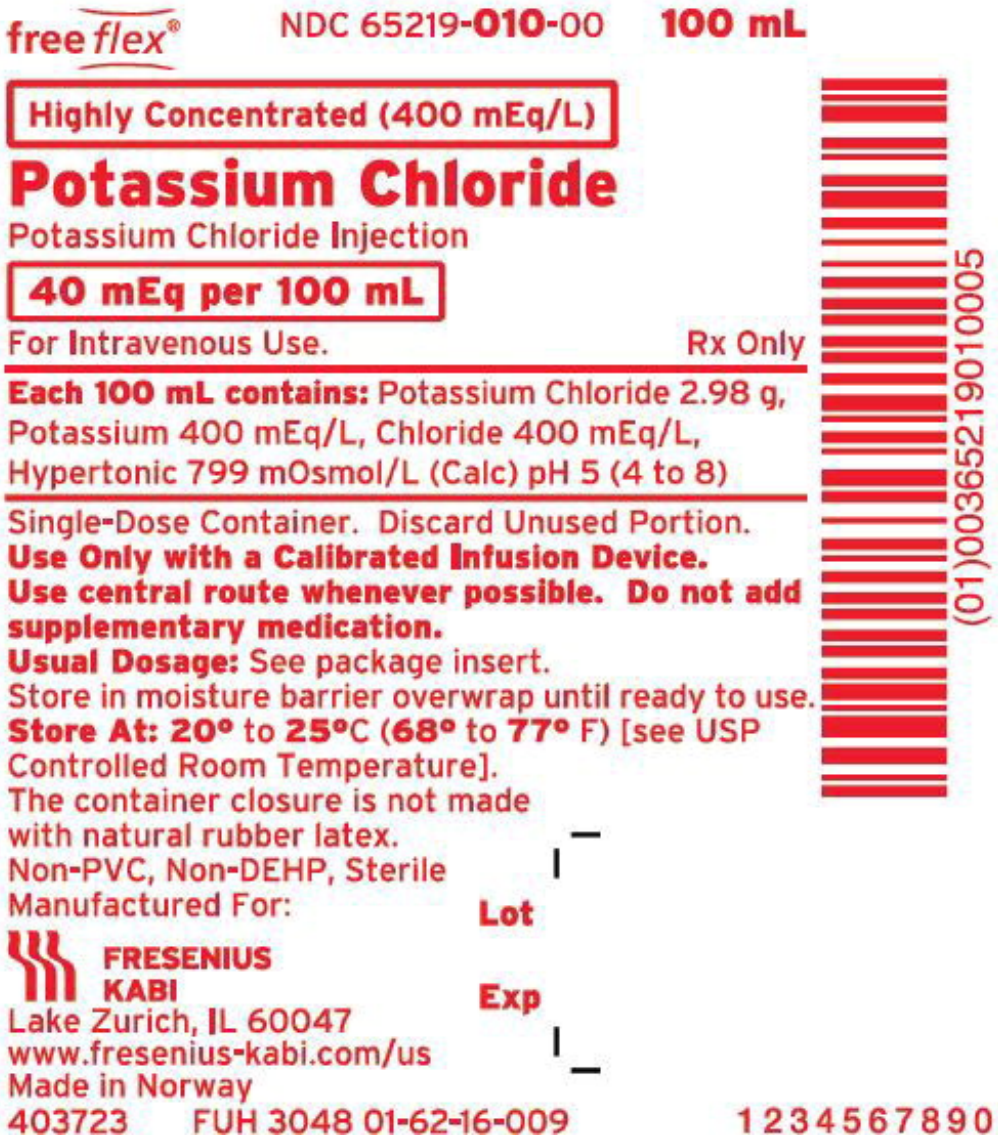
Potassium Chloride

Potassium Chloride Injection

40 mEq per 100 mL

For Intravenous Use.

Rx only



POTASSIUM CHLORIDE

potassium chloride injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65219-012
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)	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:65219-012-01	50 in 1 CARTON	06/25/2021	
1	NDC:65219-012-00	100 mL in 1 BAG; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211087	06/25/2021	

POTASSIUM CHLORIDE

potassium chloride injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65219-004
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CHLORIDE	10 meq in 50 mL

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

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:65219-004-01	60 in 1 CARTON	06/25/2021	
1	NDC:65219-	50 mL in 1 BAG; Type 2: Prefilled Drug Delivery		

1	004-00	Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211087	06/25/2021	

POTASSIUM CHLORIDE

potassium chloride injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65219-006
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CHLORIDE	20 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:65219-006-01	50 in 1 CARTON	06/25/2021	
1	NDC:65219-006-00	100 mL in 1 BAG; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211087	06/25/2021	

POTASSIUM CHLORIDE

potassium chloride injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65219-008
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CHLORIDE	20 meq in 50 mL

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

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:65219-008-51	60 in 1 CARTON	06/25/2021	
1	NDC:65219-008-50	50 mL in 1 BAG; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211087	06/25/2021	

POTASSIUM CHLORIDE

potassium chloride injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65219-010
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CHLORIDE	40 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:65219-010-01	50 in 1 CARTON	06/25/2021	
1	NDC:65219-010-00	100 mL in 1 BAG; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211087	06/25/2021	

Labeler - Fresenius Kabi USA, LLC (013547657)

Establishment

Name	Address	ID/FEI	Business Operations
Fresenius Kabi Norge AS		731170932	ANALYSIS(65219-004, 65219-012, 65219-008, 65219-006, 65219-010) , MANUFACTURE(65219-004, 65219-012, 65219-008, 65219-006, 65219-010)

Revised: 12/2023 Fresenius Kabi USA, LLC