POTASSIUM CHLORIDE- potassium chloride, dextrose monohydrate injection, solution
Fresenius Kabi USA, LLC

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use POTASSIUM CHLORIDE IN 5% DEXTROSE INJECTION safely and effectively. See full prescribing information for POTASSIUM CHLORIDE IN 5% DEXTROSE

POTASSIUM CHLORIDE IN 5% DEXTROSE injection, for intravenous use
Initial U.S. Approval: 1979

RECENT MAJOR CHANGES

Contraindications (4)	07/2019
Warnings and Precautions (5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7)	07/2019

INDICATIONS AND USAGE

Potassium Chloride in 5% Dextrose Injection is indicated as a source of water, electrolytes and calories. (1)

DOSAGE AND ADMINISTRATION

- Only for intravenous infusion. (2.1, 5.2)
- See full prescribing information for information on preparation, administration, dosing considerations and instructions for use. (2.1, 2.2, 2.3)

DOSAGE FORMS AND STRENGTHS

Injection:
10 mEq Potassium Chloride in 5% Dextrose Injection, USP in a 1000 mL single-dose flexible container.
20 mEq Potassium Chloride in 5% Dextrose Injection, USP in a 1000 mL single-dose flexible container. (3)

CONTRAINDICATIONS

- Known hypersensitivity to potassium chloride or dextrose (4, 5.1)
- Clinically significant hyperkalemia (4, 5.2)
- Clinically significant hyperglycemia (4, 5.3)

WARNINGS AND PRECAUTIONS

- Hypersensitivity Reactions: monitor for signs and symptoms and discontinue infusion if reactions occur. (5.1)
- Hyperkalemia: May result in cardiac arrhythmias. Avoid use in patients with, or at risk for, hyperkalemia. If use cannot be avoided, use a product with a low amount of potassium chloride, infuse slowly and monitor serum potassium concentrations and ECGs. (5.2)
- Hyperglycemia or Hyperosmolar Hyperglycemic State: Monitor blood glucose and administer insulin as needed. (5.3, 8.4)
- Hyponatremia: Avoid in patients with or at risk for hyponatremia. If use cannot be avoided, monitor serum sodium concentrations. (5.4, 8.4)
- Hypokalemia: Avoid in patients with or at risk for hypokalemia. If use cannot be avoided, monitor serum potassium levels. (5.5)
- Fluid Overload: Avoid in patients with or at risk for fluid and/or solute overloading. If use cannot be avoided, monitor daily fluid balance and electrolyte, concentrations and acid-base balance, as needed and especially during prolonged use. (5.6)
- Refeeding Syndrome: Monitor severely undernourished patients and slowly increase nutrient intake. (5.7)

ADVERSE REACTIONS

Adverse reactions include electrolyte imbalances, hyperglycemia, and hypervolemia and injection site reactions. (6)
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.

DRUG INTERACTIONS

- Other Products that Cause Hyperkalemia: Avoid use in patients receiving such products. If use cannot be avoided, monitor serum potassium concentrations. (7.1)
- Other Products that Affect Glycemic Control, Vasopressin or Fluid and/or Electrolyte Balance: Monitor blood glucose concentrations, fluid balance serum electrolyte concentrations and acid-base balance. (7.2)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 1/2021

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Potassium Chloride in 5% Dextrose Injection is indicated as a source of water, electrolytes and calories.

2 DOSAGE AND ADMINISTRATION

2.1 Important Administration Instructions

- Potassium Chloride in 5% Dextrose Injection is only for intravenous infusion *[see Warnings and Precautions (5.2)]*.
- For patients receiving Potassium Chloride in 5% Dextrose Injection at greater than maintenance rates, frequent monitoring of serum potassium concentrations and serial electrocardiograms (ECGs) are recommended.
- The osmolarity of 10 mEq Potassium Chloride in 5% Dextrose Injection is 272 mOsmol/L (calc). The osmolarity of 20 mEq Potassium Chloride in 5% Dextrose is 293 mOsmol/L (calc). Peripheral administration is generally acceptable; however; consider central vein administration if there is peripheral vein irritation, phlebitis, and/or associated pain.
- Do not administer Potassium Chloride in 5% Dextrose Injection simultaneously with blood products through the same administration set because of the possibility of pseudo agglutination or hemolysis.
- To prevent air embolism, use a non-vented infusion set or close the vent on a vented set, avoid multiple connections, do not connect flexible containers in series, fully evacuate residual gas in the container prior to administration, do not pressurize the flexible container to increase flow rates, and if administration is controlled by a pumping device, turn off pump before the container runs dry.
- Prior to infusion, visually inspect the solution for particulate matter. The solution should be clear and there should be no precipitates. Do not administer unless solution is clear and container is undamaged.
- Use of a final filter is recommended during administration of parenteral solutions, where possible.

2.2 Recommended Dosage

The infusion rate and volume depends on the age, weight, clinical and metabolic conditions of the patient and concomitant therapy. Electrolyte supplementation may be indicated according to the clinical needs of the patient. The administration rate should be governed, especially for premature infants with low birth weight, during the first few days of therapy, by the patient's tolerance to dextrose. Increase the infusion rate gradually as indicated by frequent monitoring of blood glucose concentrations *[see Warnings and Precautions (5.1), Use in Specific Populations (8.4)]*.

2.3 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.

Flexible Plastic Container (**free***flex*® bag)

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. Check to ensure the solution is clear and there are no precipitates. Discard if there is a color change and/or the appearance of precipitates.

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.
6. Suspend solution container from hanger hole.

To Add Medication

- Additives may be incompatible. Complete information is not available. Do not use additives known or determined to be incompatible.
- Before adding a substance or medication, verify that it is soluble and/or stable in this drug product and that the pH range of this drug product is appropriate.
- Consult with pharmacist, if available. If, in the informed judgment of the healthcare provider, it is deemed advisable to introduce additives, use aseptic technique.
- When introducing additives, consult the instructions for use of the medication to be added and other relevant literature.

To Add Medication Prior to Solution Administration

1. Identify WHITE Additive Port with arrow pointing toward container.
2. Immediately before injecting additives, break off WHITE Additive Port Cap with the arrow pointing toward container.
3. Hold base of WHITE Additive Port horizontally.
4. Prepare medication site
5. Insert an 18 to 23 gauge needle horizontally through the center of WHITE Additive Port's septum and inject additives.
6. Mix container contents thoroughly.
   For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.
7. After addition, check to ensure the solution is clear and there are no precipitates. Discard if there is a color change and/or the appearance of precipitates.

To Add Medication During Solution Administration

1. Close the clamp on the set
2. Identify WHITE Additive Port with arrow pointing toward container
3. Immediately before injecting additives, if the Cap has not been broken off, break off WHITE Additive Port cap with the arrow pointing toward container.
4. Hold base of WHITE Additive Port horizontally.

5. Prepare medication site.
6. Using a syringe with an 18 to 23 gauge needle, horizontally insert through the center of WHITE Additive Port's septum and inject additives.
7. Remove container from IV pole and/or turn to an upright position.
8. Mix container contents thoroughly.
9. After addition, check to ensure the solution is clear and there are no precipitates. Discard if there is a color change and/or the appearance of precipitates.
10. Using aseptic technique, repeat steps 4-7 as necessary.
11. Return container to in use position and continue administration.

Storage

- Use promptly; do not store solutions containing additives.
- Single-dose container.
- Discard any unused portion.

3 DOSAGE FORMS AND STRENGTHS

Potassium Chloride in 5% Dextrose Injection, USP is a clear solution in a 1000 mL single-dose, flexible container (**free***flex*®):

- 10 mEq Potassium Chloride and 5% Dextrose
- 20 mEq Potassium Chloride and 5% Dextrose

4 CONTRAINDICATIONS

Potassium Chloride in 5% Dextrose Injection is contraindicated in patients with:

- known hypersensitivity to potassium chloride and/or dextrose *[see Warnings and Precautions 5.1)]*
- clinically significant hyperkalemia *[see Warnings and Precautions (5.2)]*
- clinically significant hyperglycemia *[see Warnings and Precautions (5.3)]*

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity Reactions

Hypersensitivity and infusion reactions, including anaphylaxis, have been reported with Potassium Chloride in 5% Dextrose Injection *[see Adverse Reactions (6)]*. Stop the infusion immediately if signs or symptoms of a hypersensitivity or infusion reaction develops *[see Contraindications (4)]*. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

5.2 Hyperkalemia

Potassium-containing solutions, including Potassium Chloride in 5% Dextrose Injection may increase the risk of hyperkalemia. Hyperkalemia can be asymptomatic and manifest only by increased serum potassium concentrations and/or characteristic electrocardiographic (ECG) changes. Cardiac arrhythmias, some fatal, can develop at any time during hyperkalemia.

To avoid life threatening hyperkalemia, do not administer Potassium Chloride in 5%

Dextrose Injection as an intravenous push (i.e., intravenous injection manually with a syringe connected to the intravenous access, without quantitative infusion device *[see Dosage and Administration (2.1)]*.

Patients at increased risk of developing hyperkalemia and cardiac arrhythmias include those:

- with severe renal impairment, acute dehydration, extensive tissue injury or burns, and certain cardiac disorders such as congestive heart failure or AV block (especially if they receive digoxin).
- with hyperosmolality, acidosis, or undergoing correction of alkalosis (conditions associated with a shift of potassium from intracellular to extracellular space).
- treated concurrently or recently with agents or products that can cause or increase the risk of hyperkalemia *[see Drug Interactions (7.1)]*.

Avoid use of Potassium Chloride in 5% Dextrose Injection in patients with, or at risk for, hyperkalemia. If use cannot be avoided, use a product with a low amount of potassium chloride, infuse slowly and monitor serum potassium concentrations and ECGs.

5.3 Hyperglycemia and Hyperosmolar Hyperglycemic State

The use of dextrose infusions in patients with impaired glucose tolerance may worsen hyperglycemia. Administration of dextrose at a rate exceeding the patient's utilization rate may lead to hyperglycemia, coma, and death.

Hyperglycemia is associated with an increase in serum osmolality, resulting in osmotic diuresis, dehydration and electrolyte losses *[see Warnings and Precautions (5.6)]*.

Patients with underlying central nervous system disease and renal impairment who receive dextrose infusions, may be at greater risk of developing hyperosmolar hyperglycemic state.

Monitor blood glucose concentrations and treat hyperglycemia to maintain concentrations within normal limits while administering Potassium Chloride in 5% Dextrose Injection.

Insulin may be administered or adjusted to maintain optimal blood glucose concentrations.

5.4 Hyponatremia

Potassium Chloride in 5% Dextrose Injection is an isotonic solution *[see Description, Table 1 (11)]*. In the body, however, glucose containing fluids can become extremely physiologically hypotonic due to rapid glucose metabolization. Monitoring of serum sodium is particularly important for hypotonic fluids.

Depending on the tonicity of the solution, the volume and rate of infusion, and depending on a patient's underlying clinical condition and capability to metabolize glucose, intravenous administration of glucose can cause electrolyte disturbances, most importantly hypo- or hyperosmotic 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). Close clinical monitoring may be warranted.

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. Patients at increased risk for developing complications of hyponatremia, such as hyponatremic encephalopathy include pediatric patients; women, in particular, premenopausal women; patients with hypoxemia; and in patients with underlying central nervous system disease *[see Use in Specific Populations (8.4, 8.5)]*.

Rapid correction of hyponatremia is potentially dangerous with risk of serious neurologic complications such as osmotic demyelination syndrome with risk of seizures and cerebral edema. To avoid complications, monitor serum sodium and chloride concentrations, fluid status, acid-base balance, and signs of neurologic complications.

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.

5.5 Hypokalemia

Infusion of Potassium Chloride in 5% Dextrose Injection may result in hypokalemia, leading to arrhythmias, muscle weakness, paralysis, heart block, and rhabdomyolysis.

Hypokalemic periodic paralysis, metabolic alkalosis, increased gastrointestinal losses (e.g., diarrhea, vomiting), prolonged low potassium diet or primary hyperaldosteronism may increase the risk of hypokalemia. If use cannot be avoided, monitor serum potassium levels.

5.6 Fluid Overload

Depending on the volume and rate of infusion, the patient's underlying clinical condition and capability to metabolize dextrose, intravenous administration of Potassium Chloride in 5% Dextrose and Sodium Chloride Injection can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema.

Avoid Potassium Chloride in 5% Dextrose 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.

5.7 Refeeding Syndrome

Refeeding severely undernourished patients may result in the refeeding syndrome that is characterized by the shift of potassium, phosphorus, and magnesium intracellularly as the patient becomes anabolic. Thiamine deficiency and fluid retention may also develop. To prevent these complications, monitor severely undernourished patients and slowly increasing nutrient intake.

6 ADVERSE REACTIONS

The following adverse reactions associated with the use of Potassium Chloride in 5% Dextrose Injection were identified in post marketing reports. Because these reactions were reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

The following clinically significant adverse reactions are described elsewhere in the labeling:

- *Hypersensitivity reactions*: including anaphylaxis and chills *[see Warnings and Precautions (5.1)]*.
- Hyperkalemia, including cardiac arrest, as a manifestation *[see Warnings and Precautions (5.2)]*
- Hyponatremia and hyponatremic encephalopathy *[see Warnings and Precautions (5.4)]*
- Hypokalemia *[see Warnings and Precautions (5.5)]*
- Hypervolemia *[see Warnings and Precautions (5.6)]*
- *Injection site reactions*: infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation, infusion site rash, infusion site pain, infusion site vesicles, infusion site pruritus, pyrexia and chills

7 DRUG INTERACTIONS

7.1 Other Products that Cause Hyperkalemia

Administration of Potassium Chloride in 5% Dextrose 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, angiotensin-converting enzyme inhibitors, angiotensin receptor blockers) increases the risk of severe and potentially fatal hyperkalemia, in particular in the presence of other risk factors for hyperkalemia *[see Warnings and Precautions (5.2)]*. Avoid use of Potassium Chloride in 5% Dextrose Injection in patients receiving such products. If use cannot be avoided, monitor serum potassium concentrations.

7.2 Other Products that Affect Glycemic Control, Vasopressin or Fluid and/or Electrolyte Balance

Potassium Chloride in 5% Dextrose Injection can affect glycemic control, vasopressin and fluid and/or electrolyte balance *[see Warnings and Precautions (5.3, 5.4, 5.5, 5.6)]*.

Monitor blood glucose concentrations, fluid balance, serum electrolyte concentrations and acid-base balance when using Potassium Chloride in 5% Dextrose Injection in patients treated with other substances that affect glycemic control, vasopressin or fluid and/or electrolyte balance.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Appropriate administration of Potassium Chloride in 5% Dextrose Injection during pregnancy is not expected to cause adverse developmental outcomes, including congenital malformations. Animal reproduction studies have not been conducted with Potassium Chloride in 5% Dextrose Injection.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or

other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

8.2 Lactation

Risk Summary

Potassium is present in human breast milk. There are no data on the effects of Potassium Chloride in 5% Dextrose Injection on a breastfed infant or the effects on milk production.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Potassium Chloride in 5% Dextrose Injection and any potential adverse effects on the breastfed infant from Potassium Chloride in 5% Dextrose Injection or from the underlying maternal condition.

8.4 Pediatric Use

The safety profile of Potassium Chloride in 5% Dextrose Injection in pediatric patients is similar to adults.

Neonates, especially premature infants with low birth weight, are at increased risk of developing hypo- or hyperglycemia and therefore need close monitoring during treatment with intravenous glucose solutions to ensure adequate glycemic control in order to avoid potential long term adverse effects.

Closely monitor plasma electrolyte concentrations in pediatric patients who may have impaired ability to regulate fluids and electrolytes. In very low birth weight infants, excessive or rapid administration of Potassium Chloride in 5% Dextrose Injection may result in increased serum osmolality and risk of intracerebral hemorrhage.

Children (including neonates and older children) are at increased risk of developing hyponatremia as well as for developing hyponatremic encephalopathy.

8.5 Geriatric Use

Potassium Chloride in 5% Dextrose Injection is known to be substantially excreted by the kidney, and the risk of adverse reactions to this product may be greater in patients with impaired renal function *[see Warnings and Precautions (5.2, 5.3)]*.

Elderly patients are at increased risk of developing hyponatremia as well as for developing hyponatremic encephalopathy *[see Warnings and Precautions (5.4)]*.

Dose selection for an elderly patient should be cautious, 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.

8.6 Renal Impairment

Administration of Potassium Chloride in 5% Dextrose Injection in patients with renal impairment may result in hyperkalemia, hyponatremia, and/or fluid overload. Monitor patients with renal impairment for development of these adverse reactions *[see Warnings and Precautions (5.2, 5.4, 5.6)]*.

10 OVERDOSAGE

Excess administration of Potassium Chloride in 5% Dextrose Injection can cause:

Hyperkalemia

- Manifestations of hyperkalemia may include:
  - disturbances in cardiac conduction and arrhythmias, including bradycardia, heart block, asystole, ventricular tachycardia, ventricular fibrillation, and ECG changes (peaking of T waves, loss of P waves, and QRS widening)
  - hypotension,
  - muscle weakness up to and including muscular and respiratory paralysis, paresthesia of extremities,
  - gastrointestinal symptoms (ileus, nausea, vomiting, abdominal pain)

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

If hyperkalemia is present or suspected, discontinue the infusion immediately and institute close ECG, laboratory and other monitoring and, as necessary, corrective therapy to reduce serum potassium concentrations *[see Warnings and Precautions (5.2)]*.

Other Electrolyte and Fluid Disorders

- Hyperglycemia, hyperosmolality, and adverse effects on water and electrolyte balance, and corresponding complications, which can be fatal *[see Warnings and Precautions (5.3, 5.6)]*.
- Hyponatremia, manifestations may include seizures, coma, cerebral edema and death) *[see Warnings and Precautions (5.4)]*.
- Fluid overload (which can lead to central and/or peripheral edema) *[see Warnings and Precautions (5.6)]*.
- Hypernatremia, especially in patients with severe renal impairment.

Interventions include discontinuation of the infusion, dose reduction, monitoring of fluid balance, electrolyte concentrations and acid-base balance and institution of appropriate corrective measures such as administration of exogenous insulin.

11 DESCRIPTION

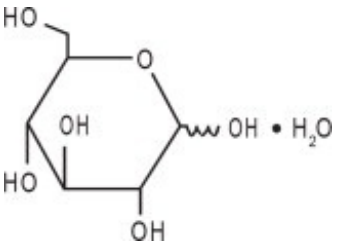
Potassium Chloride in 5% Dextrose Injection, USP is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment and caloric supply in a single-dose container for intravenous administration. It contains no antimicrobial agents. Composition, osmolarity, pH, ionic concentration and caloric content are shown in Table 1.

Table 1

	Size (mL)	Composition (g/L)				Ionic Concentration (mEq/L)		Caloric Content (kcal/L)
Potassium Chloride in 5% Dextrose Injection,		**Dextrose Hydrous, USP	Potassium Chloride, USP (KCl)	*Osmolarity (mOsmol/L) (calc.)	pH	**Potassium**	Chloride	

USP mEq Potassium								
10 mEq	1000	50	0.75	272	4.5 (3.5 to 6.5)	**10**	10	170
20 mEq	1000	50	1.5	293	4.5 (3.5 to 6.5)	**20**	20	170

* Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L.
**



D-Glucose monohydrate

Dextrose is derived from corn.

The flexible plastic container is fabricated from a specially formulated nonplasticized, film containing polypropylene and thermoplastic elastomers (**free***flex*® bag). The amount of water that can permeate from 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.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Potassium Chloride in 5% Dextrose Injection is a source of water, electrolytes and calories. It is capable of inducing diuresis depending on the clinical condition of the patient.

16 HOW SUPPLIED/STORAGE AND HANDLING

Potassium Chloride in 5% Dextrose Injection, USP is a clear solution in 1000 mL single-dose, flexible containers available as follows:

Product code	Unit of Use	Strength	Unit of Sale
667110	NDC 63323-667-01 One 1000 mL **free***flex*®	10 mEq Potassium	NDC 63323-667-10 Package of 10 **free***flex*®

	Bag		Bags
669110	NDC 63323-669-01 One 1000 mL **free***flex*® Bag	20 mEq Potassium	NDC 63323-669-10 Package of 10 **free***flex*® Bags

Avoid excessive heat. Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]; brief exposure up to 40°C does not adversely affect the product.

The container closure is not made with natural rubber latex. Non-PVC, Non-DEHP, Sterile.

17 PATIENT COUNSELING INFORMATION

Inform patients, caregivers or home healthcare providers of the following risks of Potassium Chloride in 5% Dextrose Injection:

- Hypersensitivity reactions *[see Warnings and Precautions (5.1)]*
- Hyperkalemia *[see Warnings and Precautions (5.2)]*
- Hyperglycemia and hyperosmolar hyperglycemic state *[see Warnings and Precautions (5.3)]*
- Hyponatremia *[see Warnings and Precautions (5.4)]*
- Hypokalemia *[see Warnings and Precautions (5.5)]*
- Fluid overload *[see Warnings and Precautions (5.6)]*
- Refeeding syndrome *[see Warnings and Precautions (5.7)]*

Manufactured for:

FRESENIUS KABI

Lake Zurich, IL 60047

Made in Norway

www.fresenius-kabi.com/us

451697

PACKAGE LABEL - PRINCIPAL DISPLAY – Potassium Chloride in 5% Dextrose Injection, USP 10 mEq/L Bag Label

freeflex NDC 63323-**667**-01 **1000 mL**

10 mEq Potassium Chloride

(10 mEq/L)

Potassium Chloride in 5% Dextrose

Injection, USP

For Intravenous Use. Rx Only

100 free flex® NDC 63323-667-01 **1000 mL**

200

10 mEq Potassium Chloride

(10 mEq/L)
Potassium Chloride in 5% Dextrose Injection, USP

For Intravenous Use. Rx Only

300

Each 100 mL contains: Dextrose Hydrous 5 g; Potassium Chloride 75 mg.

Electrolytes per 1000 mL: Potassium 10 mEq; Chloride 10 mEq.

272 mOsmol/L (calc.). pH 4.5 (3.5 to 6.5) mEq

400

Single-Dose Container. Discard Unused Portion.

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

500

Usual dosage: See package insert.
The overwrap is a moisture barrier.
Use immediately once removed from overwrap.

STORE AT: 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Avoid excessive heat.

The container closure is not made with natural rubber latex.
Non-PVC, Non-DEHP, Sterile.

600

Manufactured for:

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

403716
FUH 3164
01-62-16-003

(01)00363323667016

700

LOT

EXP

PACKAGE LABEL - PRINCIPAL DISPLAY – Potassium Chloride in 5% Dextrose Injection, USP 10 mEq/L Shipper Label

NDC 63323-667-10 667110

10 mEq Potassium Chloride

in 5% Dextrose Injection, USP

1000 mL x 10

PACKAGE LABEL - PRINCIPAL DISPLAY – Potassium Chloride in 5% Dextrose Injection, USP 20 mEq/L Bag Label

freeflex NDC 63323-**669**-01 **1000 mL**

20 mEq Potassium Chloride

(20 mEq/L)

Potassium Chloride in 5% Dextrose

Injection, USP

For Intravenous Use. Rx Only

100 free flex® NDC 63323-669-01 **1000 mL**

200

20 mEq Potassium Chloride

(20 mEq/L)
Potassium Chloride in 5% Dextrose Injection, USP

For Intravenous Use. Rx Only

300

Each 100 mL contains: Dextrose Hydrous 5 g; Potassium Chloride 150 mg.

Electrolytes per 1000 mL: Potassium 20 mEq; Chloride 20 mEq.

293 mOsmol/L (calc.). pH 4.5 (3.5 to 6.5) mEq

400

Single-Dose Container. Discard Unused Portion.

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

500

Usual dosage: See package insert.
The overwrap is a moisture barrier.
Use immediately once removed from overwrap.

STORE AT: 20° to **25°**C (**68°** to **77°**F) [see USP Controlled Room Temperature]. Avoid excessive heat.

The container closure is not made with natural rubber latex.
Non-PVC, Non-DEHP, Sterile.

600

Manufactured for:

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

403718
FUH 3174
01-62-16-004

(01)00363323669010

700

LOT

EXP

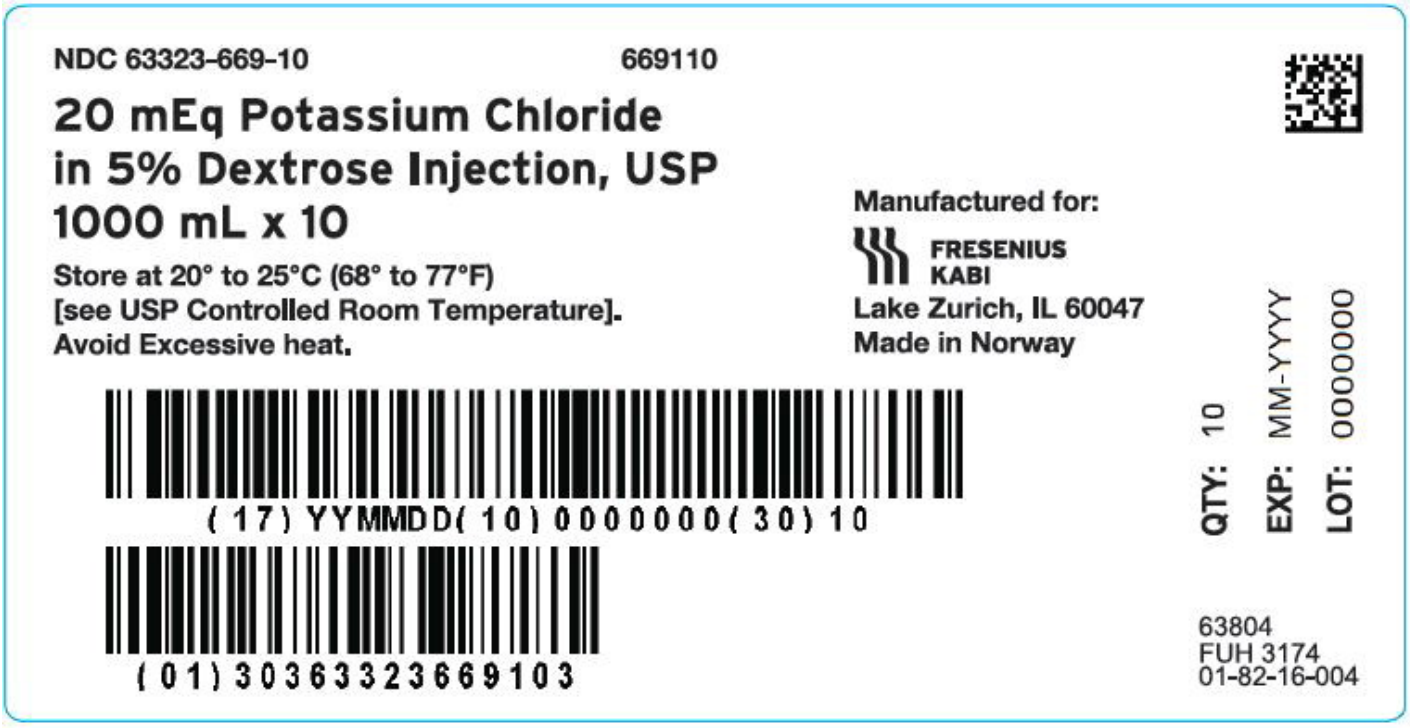
PACKAGE LABEL - PRINCIPAL DISPLAY – Potassium Chloride in 5% Dextrose Injection, USP 20 mEq/L Shipper Label

NDC 63323-669-10 669110

20 mEq Potassium Chloride

in 5% Dextrose Injection, USP

1000 mL x 10



POTASSIUM CHLORIDE

potassium chloride, dextrose monohydrate injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:63323-667
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	75 mg in 100 mL
Dextrose Monohydrate (UNII: LX22YL083G) (Anhydrous Dextrose - UNII:5SL0G7R0OK)	Dextrose Monohydrate	5 g in 100 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:63323-667-10	10 in 1 CASE	04/23/2021	
1	NDC:63323-667-01	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
ANDA	ANDA212346	04/23/2021	

POTASSIUM CHLORIDE

potassium chloride, dextrose monohydrate injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:63323-669
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	150 mg in 100 mL
Dextrose Monohydrate (UNII: LX22YL083G) (Anhydrous Dextrose - UNII:5SL0G7R0OK)	Dextrose Monohydrate	5 g in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63323-669-10	10 in 1 CASE	04/23/2021	
1	NDC:63323-669-01	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
ANDA	ANDA212346	04/23/2021	

Labeler - Fresenius Kabi USA, LLC (608775388)

Establishment

Name	Address	ID/FEI	Business Operations
Fresenius Kabi Norge AS		731170932	ANALYSIS(63323-667, 63323-669) , MANUFACTURE(63323-667, 63323-669)