POTASSIUM CHLORIDE IN DEXTROSE- dextrose and potassium chloride solution
B. Braun Medical Inc.

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

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

RECENT MAJOR CHANGES

Contraindications (4) 07/2020
Warnings and Precautions (5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7) 07/2020

INDICATIONS AND USAGE

Potassium Chloride in Dextrose Injection is indicated as a source of electrolytes, calories, and water for hydration. (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: 20 mEq Potassium Chloride in 5% Dextrose Injection, USP in a 1000 mL plastic container. (3)

CONTRAINDICATIONS

- known hypersensitivity to potassium chloride and/or dextrose *(5.1)*
- clinically significant hyperkalemia *(5.2)*
- clinically significant hyperglycemia *(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 B. Braun Medical Inc. at 1-866-854-6851 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. (6)

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: 7/2020

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 Dextrose Injection is indicated as a source of electrolytes, calories, and water for hydration.

2 DOSAGE AND ADMINISTRATION

2.1 Important Administration Instructions

- Potassium Chloride in Dextrose Injection is only for intravenous infusion *[see Warnings and Precautions (5.2)]*.

- For patients receiving Potassium Chloride in Dextrose Injection at greater than maintenance rates, frequent monitoring of serum potassium concentrations and serial electrocardiograms (ECGs) are recommended.
- The osmolarity of Potassium Chloride in Dextrose Injection is 295 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 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

To Open

- Tear overwrap down at notch and remove solution container.
- Visually inspect the container. The closure system has two ports; the one for the administration set has a tamper evident plastic protector and the other is a medication addition site. Evaluate the following:
- Read the label. Ensure solution is the one ordered and is within the expiration date.
- If the outlet port protector is damaged, detached or not present, discard container.
- Invert the container and check to ensure the solution is clear and there is no haze or particulate matter. Discard if there is a color change and/or the appearance of precipitates, insoluble complexes or crystals.
- Check for minute leaks by squeezing solution container firmly. If leaks are found, discard solution as sterility may be impaired.
- If supplemental medication is desired, follow directions below before preparing for administration.

Preparation for Administration

1. Remove plastic protector from sterile set port at bottom of container.
2. Attach administration set. Refer to complete directions accompanying set.

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 Potassium Chloride in Dextrose Injection and that the pH range of Potassium Chloride in Dextrose Injection 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.

To Add Medication Before Solution Administration

1. Prepare medication site.
2. Using syringe with 18-22 gauge needle, puncture medication port and inner diaphragm and inject.
3. Squeeze and tap ports while ports are upright and mix solution and medication thoroughly.
4. 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, insoluble complexes or crystals.

To Add Medication During Solution Administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 18-22 gauge needle of appropriate length (at least 5/8 inch), puncture resealable medication port and inner diaphragm and inject.
4. Remove container from IV pole and/or turn the container so the ports are in an upright position.
5. Evacuate both ports by tapping and squeezing them while container ports are in the upright position.
6. Mix solution and medication 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, insoluble complexes or crystals, do not use.
8. 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 supplied sterile and nonpyrogenic in 1000 mL single-dose, flexible container.

4 CONTRAINDICATIONS

Potassium Chloride in 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 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 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 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 alkalsis (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 (such as diabetes mellitus, renal impairment, or in the presence of sepsis, trauma, or shock) 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 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

The infusion of solutions with Potassium Chloride in 5% Dextrose Injection, USP 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 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 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 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 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 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 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 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 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 Dextrose Injection and any potential adverse effects on the breastfed infant from Potassium Chloride in Dextrose Injection or from the underlying maternal condition.

8.4 Pediatric Use

The safety profile of Potassium Chloride in 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 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 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 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 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.

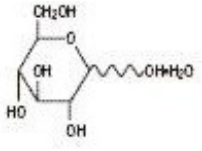
11 DESCRIPTION

(See chart below for quantitative information.)

Potassium Chloride in 5% Dextrose Injection USP is sterile, nonpyrogenic solution for fluid and

electrolyte replenishment and caloric supply. It contains no bacteriostatic or antimicrobial agents. This product is intended for intravenous administration.

The formulas of the active ingredients are:

Ingredients	Molecular Formula	Molecular Weight
Potassium Chloride USP	KCl	74.55
Hydrous Dextrose USP		198.17

Composition – Each 100 mL contains:			Concentration of Electrolytes (mEq/liter)		Calories per liter	Calculated Osmolarity mOsmol/liter	pH
Solution	Hydrous Dextrose USP	Potassium Chloride USP	Potassium	Chloride			
0.15% Potassium Chloride in 5% Dextrose Injection USP	5 g	0.15 g	20	20	170	295	4.3 (3.5-6.5)
Water for Injection USP qs							

Dextrose is derived from corn.

The plastic container is made from a multilayered film specifically developed for parenteral drugs. It contains no plasticizers and exhibits virtually no leachables. The solution contact layer is a rubberized copolymer of ethylene and propylene. The container is nontoxic and biologically inert. The container-solution unit is a closed system and is not dependent upon entry of external air during administration. The container is overwrapped to provide protection from the physical environment and to provide an additional moisture barrier when necessary.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Potassium Chloride in 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 supplied sterile and nonpyrogenic in 1000 mL EXCEL® Containers packaged 12 per case.

REF	Size	NDC	mEq Potassium	Product Name
L6250	1000 mL	0264-7625-00 (Canada DIN 01931539)	20 mEq	Potassium Chloride in 5% Dextrose Injection, USP

Not made with natural rubber latex, PVC or DEHP.

Storage

Avoid excessive heat. Protect from freezing. Store at room temperature (25°C); brief exposure up to 40°C does not adversely affect the product.

Storage in automated dispensing machines: Brief exposure up to 2 weeks to ultraviolet or fluorescent light does not adversely affect the product labeling legibility; prolonged exposure can cause fading of the red label. Rotate stock frequently.

17 PATIENT COUNSELING INFORMATION

Inform patients, caregivers or home healthcare providers of the following risks of Potassium Chloride in 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)]*

Rx Only

EXCEL is a registered trademark of B. Braun Medical Inc.

B. Braun Medical Inc.
Bethlehem, PA 18018-3524 USA
1-800-227-2862

In Canada, distributed by:
B. Braun of Canada, Ltd.
Scarborough, Ontario M1H 2W4

Y36-002-975 LD-235-3

PRINCIPAL DISPLAY PANEL - 1000 mL Container

0.15% Potassium Chloride in 5% Dextrose Injection USP

REF L6250

NDC 0264-7625-00

DIN 01931539

1000 mL
EXCEL® CONTAINER

20 mEq K+/liter

Y94-003-344 LD-503-2

Each 100 mL contains: Hydrous Dextrose USP 5 g; Potassium Chloride USP 0.15 g; Water for Injection USP qs

pH: 4.3 (3.5-6.5); Calc. Osmolarity: 295 mOsmol/liter

Electrolytes (mEq/liter): K^+ 20; Cl^- 20

Sterile, nonpyrogenic. Single dose container. Do not use in series connection. For intravenous use only. Use only if solution is clear and container and seals are intact.

WARNINGS: Some additives may be incompatible. Consult with pharmacist. When introducing

additives, use aseptic techniques.
Mix thoroughly. Do not store.

Recommended Storage: Room temperature (25°C). Avoid excessive heat. Protect from freezing. See Package Insert.

Do not remove 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.

Not made with natural rubber latex, PVC or DEHP.

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Rx only

B. Braun Medical Inc.
Bethlehem, PA 18018-3524 USA
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In Canada, distributed by:
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Scarborough, Ontario M1H 2W4
Y94-003-267 LD-168-2

EXP
LOT

0.15% Potassium Chloride in 5% Dextrose Injection USP

REF L6250
NDC 0264-7625-00
DIN 01931539

1000 mL
EXCEL® CONTAINER

20 mEq K^+/liter

Y94-003-344 LD-503-2

Each 100 mL contains: Hydrous Dextrose USP 5 g; Potassium Chloride USP 0.15 g; Water for Injection USP qs

pH: 4.3 (3.5-6.5); Calc. Osmolarity: 295 mOsmol/liter

Electrolytes (mEq/liter): K^+ 20; Cl^- 20

Sterile, nonpyrogenic. Single dose container. Do not use in series connection. For intravenous use only. Use only if solution is clear and container and seals are intact.

WARNINGS: Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

Recommended Storage: Room temperature (25°C). Avoid excessive heat. Protect from freezing. See Package Insert.

Do not remove 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.

Not made with natural rubber latex, PVC or DEHP. Rx only

7 OTHER

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BARCODE

BARCODE

Y94-003-267 LD-168-2

B|BRAUN

B. Braun Medical Inc.
Bethlehem, PA 18018-3524 USA
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Scarborough, Ontario M1H 2W4

EXP LOT

POTASSIUM CHLORIDE IN DEXTROSE

dextrose and potassium chloride solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0264-7625
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROSE (UNII: IY9XDZ35W2) (DEXTROSE - UNII:IY9XDZ35W2)	DEXTROSE	5 g in 100 mL
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CHLORIDE	0.15 g in 100 mL

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

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0264-7625-00	12 in 1 CASE	09/29/1989	
1		1000 mL in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019699	09/29/1989	

POTASSIUM CHLORIDE IN DEXTROSE

dextrose and potassium chloride solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0264-7628
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROSE (UNII: IY9XDZ35W2) (DEXTROSE - UNII:IY9XDZ35W2)	DEXTROSE	5 g in 100 mL
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CHLORIDE	0.3 g in 100 mL

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0264-7628-00	12 in 1 CASE	09/29/1989	03/31/2014
1		1000 mL in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019699	09/29/1989	

Labeler - B. Braun Medical Inc. (002397347)

Revised: 7/2020 B. Braun Medical Inc.