PRODUCT MONOGRAPH

INCLUDING PATIENT MEDICATION INFORMATION

Potassium Chloride Injection

Potassium ion (K+), Sterile Solution

10 mEq/50mL, 20 mEq/50mL, 10 mEq/100mL, 20 mEq/100mL and 40mEq/100mL

Intravenous

Electrolyte Replenisher

Baxter Corporation

Mississauga, Ontario

L5N 0C2 Canada

Date of Initial Authorization:
Oct 08,2000

Date of Revision:
JAN 12, 2022

Submission Control Number: 252640

RECENT MAJOR LABEL CHANGES

7 WARNINGS AND PRECAUTIONS	01/2022

TABLE OF CONTENTS

Sections or subsections that are not applicable at the time of authorization are not listed .

PART I: HEALTH PROFESSIONAL INFORMATION

1 INDICATIONS

Potassium Chloride Injection is indicated for:

- treatment of potassium deficiency states where hypokalemia is severe. Severe hypokalemia is defined as a serum potassium concentration of less than 2.5 mEq/L; serum potassium less than 3.0 mEq/L with definite symptoms or ECG signs of hypokalemia; or serum potassium less than 3.2 mEq/L in the presence of metabolic acidosis and treatment with sodium bicarbonate or insulin is imminent.
- treatment of hypokalemia ($K^+ < 3.5$ mEq/L) in postoperative cardiothoracic surgical patients, where a serum potassium concentration of 4.0 to 5.0 mEq/L is necessary to minimize ventricular arrhythmias.
- cautious treatment to abolish arrhythmias of cardiac glycoside toxicity precipitated by a loss of potassium. This regimen should not be used in patients with atrioventricular block.

This highly concentrated, ready-to-use potassium chloride injection is intended for the rapid correction of hypokalemia and for potassium supplementation in fluid restricted patients who cannot accommodate additional volumes of fluid associated with potassium solutions of lower concentration.

1.1 Pediatrics (< 16 years of age):

No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use.

1.2 Geriatrics (> 65 years of age):

No data are available to Health Canada; therefore, Health Canada has not authorized an indication for geriatric use.

2 CONTRAINDICATIONS

- Potassium Chloride Injection is contraindicated in patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container. For a complete listing, *see* 6 DOSAGE FORMS, STRENGTHS, COMPOSITION, AND PACKAGING.
- Hyperkalemia
- Renal impairment with oliguria, anuria or azotemia
- Untreated Addison's disease
- Ventricular fibrillation
- Salt-losing adrenal hyperplasia
- Extensive tissue breakdown as in severe burns, acute dehydration and heat cramps
- Increased sensitivity to potassium administration (e.g., in congenital paramyotonia or adynamia episodica hereditaria)

- Hyperadrenalism associated with adrenogential syndrome.
- Digitalis-induced second- or third-degree heart block is the only type of dysrhythmia in which potassium is contraindicated.

3 SERIOUS WARNINGS AND PRECAUTIONS BOX

Serious Warnings and Precautions

- 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: 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 9.4 Drug-Drug Interactions).

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

4 DOSAGE AND ADMINISTRATION

4.1 Dosing Considerations

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

4.2 Recommended Dose and Dosage Adjustment

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/L.

In urgent cases where the serum potassium level is less than 2.0 mEq/L or where severe hypokalemia is a threat, (serum potassium level less than 2.0 mEq/L and ECG 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 ECG and frequent serum K+ determinations to avoid hyperkalemia and cardiac arrest.

Health Canada has not authorized an indication for pediatric use.

4.4 Administration

For intravenous use only. Administer only with a calibrated infusion device at a slow, controlled rate. The higher concentrations (300 mEq/L and higher) should be exclusively administered via central intravenous route. Because pain and phlebitis associated with peripheral infusion of potassium chloride solutions has been reported, administration via a central route for all concentrations is recommended for thorough dilution by the blood stream and avoidance of extravasation. Correct placement of the catheter should be verified before administration.

Parenteral drug products should be inspected visually for particulate matter and discolouration, whenever solution and container permit. Do not administer unless the solution is clear, and the seal is intact. Use of a final filter is recommended during administration of all parenteral solutions where possible. Do not add supplementary medication.

4.5 Missed Dose

If you miss your scheduled infusion, contact your doctor or nurse as soon as possible to schedule your next treatment.

5 OVERDOSAGE

Symptoms: If excretory mechanisms are impaired or if potassium is administered too rapidly i.v., potentially fatal hyperkalemia can result. Paresthesia of the extremities, listlessness, mental confusion, gastrointestinal symptoms (ileus, nausea, vomiting, abdominal pain), weakness, heaviness of legs, muscular and respiratory paralysis, hypotension, disturbances in cardiac conduction and arrhythmias, including bradycardia, heart block, asystole, ventricular tachycardia, ventricular fibrillation, and cardiac arrest may occur. Frequently, hyperkalemia is asymptomatic and may be manifested only by increased serum potassium concentration and, possibly, characteristic electrocardiographic changes. However, fatal arrhythmias can develop at any time.

In addition to arrhythmias and conduction disorders, progressive ECG changes occur with increasing potassium levels. Possible changes include peaking of T waves, loss of P waves, depression of S-T segment, and prolongation of the QT interval. Late manifestations include muscle paralysis and cardiovascular collapse from cardiac arrest. However, the correlation between potassium levels and ECG changes is not precise, and whether or at which potassium level certain ECG 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 ECG findings that are suspected to be caused by hyperkalemia should be considered a medical emergency.

Treatment: In the event that hyperkalemia is present or suspected, discontinue potassium i.v. administration immediately and institute corrective therapy to reduce serum potassium levels as necessary. The serum potassium concentration and ECG must be monitored, as well as serum electrolytes, creatinine, glucose and arterial blood gases.

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

1. Elimination of potassium-rich foods, medications and i.v. solutions containing potassium, or medication which can induce hyperkalemia.

2. 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.
3. Correction of acidosis, if present, with 40-160 mEq of i.v. sodium bicarbonate infused over 5 minutes. This dose may be repeated after 10-15 minutes if ECG abnormalities persist.
4. Absorption and exchange of potassium using sodium or ammonium cycle cation exchange resin, orally and as retention enema.
5. Use of hemodialysis or peritoneal dialysis.
6. Use of Calcium gluconate. I.V. calcium is not recommended in patients receiving digoxin.

In treating hyperkalemia in digitalized patients, too rapid a lowering of the serum potassium concentration can produce digitalis toxicity.

For management of a suspected drug overdose, contact your regional poison control centre.

6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

Potassium Chloride Injection is a sterile nonpyrogenic solution of Potassium Chloride, USP in Water of Injection, USP intended for intravenous administration. It contains no antimicrobial agents, and is supplied in ready to use, single dose VIAFLEX Plus plastic (polyvinyl chloride) containers.

Table 1 – Dosage Forms, Strengths, Composition and Packaging

Route of Administration	Dosage Form / Strength/Composition	Non-medicinal Ingredients
Intravenous	JB0821: sterile nonpyrogenic solution. **10 mEq/50mL.** 0.746 g Potassium Chloride, USP in q.s. Water for Injection, USP	Water for Injection
	JB0826: sterile nonpyrogenic solution. **10 mEq/100mL.** 0.746 g Potassium Chloride, USP in q.s. Water for Injection, USP	
	JB0822: sterile nonpyrogenic solution. **20 mEq/50mL.** 1.49 g Potassium Chloride, USP in q.s. Water for Injection, USP	
	JB0827: sterile nonpyrogenic solution. **20 mEq/100mL.** 1.49 g Potassium Chloride, USP in q.s. Water for Injection, USP	
	JB0824: sterile nonpyrogenic solution. 4**0 mEq/100mL.** 2.98 g Potassium Chloride, USP in q.s. Water for Injection, USP	

7 WARNINGS AND PRECAUTIONS

Please see 3 SERIOUS WARNINGS AND PRECAUTIONS BOX.

General

Potassium Chloride Injection should only be used in an ICU/CCU setting where a detailed protocol for administration of concentrated potassium chloride has been established. Uncontrolled infusion may lead to hyperkalemia.

In patients with impaired mechanisms for excreting potassium, administration of potassium chloride can produce hyperkalemia and cardiac arrest. This is of particular concern in patients given i.v. potassium. Potentially fatal hyperkalemia can develop rapidly and may be asymptomatic. To avoid potassium intoxication, do not infuse these solutions rapidly. Patients must be kept on continuous cardiac monitoring and undergo frequent testing for serum potassium and acid-base balance, especially if they receive digitalis.

Administer intravenously only with a calibrated infusion device at a slow controlled rate (*see* 4 DOSAGE AND ADMINISTRATION).

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

Administration via a central route is recommended for dilution by the blood stream and avoidance of extravasation, as well as to avoid the pain and phlebitis associated with peripheral infusion. Correct placement of the catheter should be verified before administration.

The highest concentrations of Potassium Chloride Injection (300 mEq/L and higher) should be exclusively administered via central intravenous route.

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

Cardiovascular

Administration of concentrated potassium solutions can cause cardiac conduction disorders (including complete heart block) and other cardiac arrhythmias at any time during infusion. Use potassium with caution in disease associated with heart block since increased serum potassium may increase the degree of block.

Patients requiring treatment of potassium depletion, particularly in the presence of cardiac disease, should be kept on continuous ECG monitoring and undergo clinical evaluation and frequent testing for serum potassium and acid-base balance. Continuous ECG 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. Frequently, mild or moderate hyperkalemia is asymptomatic and may be manifested only by increased serum potassium concentrations and, possibly, characteristic ECG changes. However, fatal arrhythmias can develop at any time during hyperkalemia.

Endocrine and Metabolism

Use of potassium salts in patients with adrenal insufficiency or any other condition which impairs potassium excretion requires particularly appropriate dosage adjustment. *See* 3 SERIOUS WARNINGS AND PRECAUTIONS BOX.

Potassium Chloride Injection should be used with caution in patients with or at risk of hyperchloremia and metabolic acidosis. In addition, it has been reported that hyperchloremia and acidosis may occur in patients with diabetic ketoacidosis, due to loss of bicarbonate and renal sodium chloride retention. Administration of sodium chloride-containing solutions to such patients may potentiate hyperchloremia, because of increased chloride load.

Monitoring of serum sodium is particularly important for hypotonic fluids; Potassium Chloride Injection has an osmolarity of 200-799 mOmol/L (Refer to bag label for specific osmolarity).

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

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

Monitoring and 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.

Renal

Treatment of potassium depletion, particularly in the presence of renal disease or acidosis, requires careful attention to acid base balance and appropriate monitoring of serum electrolytes, the ECG and the patient's clinical status.

Use of potassium salts in patients with chronic renal disease or any other condition which impairs potassium excretion requires particularly appropriate dosage adjustment. *See* 3 SERIOUS WARNINGS AND PRECAUTIONS BOX.

Administration of Potassium Chloride Injection may result in or precipitate acute kidney injury (AKI) by decreasing the renal blood flow, glomerular filtration rate, and by prolonging the micturition time. Plasma chloride levels and renal function should be closely monitored.

7.1 Special Populations

7.1.1 Pregnant Women

Animal reproduction studies have not been conducted with potassium chloride, and there are no adequate data from the use of Potassium Chloride Injection in pregnant women. 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, and after careful consideration of the potential risks and benefits.

7.1.2 Breast-feeding

There are no adequate data from the use of Potassium Chloride Injection in lactating women. It is unknown if the drug is excreted in human milk. Because many drugs are excreted in human milk, the potential risks and benefits for each specific patient should be carefully considered before using Potassium Chloride Injection in lactating women.

7.1.3 Pediatrics (< 16 years of age)

No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use

7.1.4 Geriatrics (> 65 years of age)

No data are available to Health Canada; therefore, Health Canada has not authorized an indication for geriatric use

8 ADVERSE REACTIONS

8.1 Adverse Reaction Overview

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 and heaviness of the legs, hypotension, cardiac arrhythmia, heart block, electrographic abnormalities and cardiac arrest. Hyperkalemia may exhibit the following ECG abnormalities: peaked T waves and a shortened QT interval when serum potassium exceeds 5.5 to 6.0 mEq/L; loss of P waves, widening of the QRS complex, and eventual asystole occurs with higher elevations. Nausea, vomiting, abdominal pain and diarrhea have been reported with the use of potassium-containing solutions.

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.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, and institute appropriate therapeutic countermeasures.

Pain associated with peripheral infusion of potassium chloride solution has been reported.

8.5 Post-Market Adverse Reactions

The following adverse reactions have been reported in the post-marketing experience. Events are listed by MedDRA System Organ Class (SOC), then by Preferred Term in order of severity, where feasible.

Table 2 – Post-market adverse reactions reported by MedRA.

Immune System Disorders:	Hypersensitivity, as manifested by rash and angioedema
Metabolism And Nutrition Disorders:	Hyperkalemia
Cardiac Disorders:	Cardiac arrest*, Asystole*, Ventricular fibrillation*, Bradycardia
Respiratory, Thoracic, And Mediastinal Disorders:	Dyspnea
General Disorders And Administration Site Conditions:	Chest pain, Infusion site pain, Infusion site irritation, Burning sensation

* as a manifestation of rapid intravenous administration and/or of hyperkalemia

Class Reactions

Other adverse reaction associated with administration of concentrated potassium chloride solutions include:

- In association with extravasation: Skin necrosis, Skin ulcer, Soft tissue necrosis, Muscle necrosis, Nerve injury, Tendon injury, and Vascular injury
- In association administration: Infusion site thrombosis, Infusion site phlebitis, Infusion site swelling, Infusion site erythema, hyponatremia, hyponatremic encephalopathy.

9 DRUG INTERACTIONS

9.1 Serious Drug Interactions

Serious Drug Interactions
• Concomitant administration of ACE inhibitors and potassium-sparing diuretics (e.g. amiloride, spironolactone, triamterene) can produce severe hyperkalemia

9.2 Drug Interactions Overview

Potassium Chloride Injection should be used with caution in patients treated concurrently or recently with agents or products that can cause hyperkalemia or increase the risk of hyperkalemia.

Administration of potassium in patients treated with such agents is associated with an increased risk of severe and potentially fatal hyperkalemia, in particular in the presence of other risk factors for hyperkalemia.

Caution is advised when administering Potassium Chloride Injection to patients treated with drugs leading to an increased vasopressin effect. The below listed drugs increase the vasopressin effect, leading to reduced renal electrolyte free water excretion and may increase the risk of hyponatremia following treatment with i.v. fluids (*See* 7 WARNINGS AND PRECAUTIONS and 8 ADVERSE REACTIONS).

Drugs stimulating vasopressin release such as chlorpropamide, clofibrate, carbamazepine, vincristine, selective serotonin reuptake inhibitors (SSRIs), 3.4-methylenedioxy-N-methamphetamine, ifosfamide, antipsychotics, opioids.

Drugs potentiating vasopressin action such as chlorpropamide, non-steroidal anti-inflammatories (NSAIDS), cyclophosphamide.

Vasopressin analogues such as desmopressin, oxytocin, vasopressin, terlipressin.

Caution is advised when administering Potassium Chloride Injection to patients treated with drugs that may increase the risk of hyponatremia, such as diuretics and antiepileptics (e.g. oxycarbazepine).

9.4 Drug-Drug Interactions

The drugs listed in this table are based on either drug interaction case reports or studies, or potential interactions due to the expected magnitude and seriousness of the interaction (i.e., those identified as contraindicated).

Table 3 - Established or Potential Drug-Drug Interactions

[Proper/Common name]	Source of Evidence	Effect	Clinical comment
ACE Inhibitors	L	Concomitant administration can produce severe hyperkalemia	Use extreme caution if administering concomitantly
Potassium-sparing diuretics (e.g. amiloride, spironolactone, triamterene)	L	Concomitant administration can produce severe hyperkalemia	Use extreme caution if administering concomitantly

Legend: L= Literature

9.5 Drug-Food Interactions

Interactions with food have not been established.

9.6 Drug-Herb Interactions

Interactions with herbal products have not been established.

9.7 Drug-Laboratory Test Interactions

Interactions with laboratory tests have not been established.

10 CLINICAL PHARMACOLOGY

10.1 Mechanism of Action

Potassium is the major cation of intracellular fluid and is essential for maintenance of acid-base balance, isotonicity, and electrodynamic characteristics of the cell. Potassium is an important activator in many enzymatic reactions and is essential to a number of physiologic processes including transmission of nerve impulses; contraction of cardiac, smooth, and skeletal muscles; gastric secretion; renal function; tissue synthesis; and carbohydrate metabolism. In addition, potassium is an important activator in many enzymatic reactions. Chloride is the major extracellular anion which is essential for the maintenance of acid-base balance. 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.

Potassium first enters the extracellular fluid and is then actively transported into the cells. In healthy adults, serum potassium concentrations generally range from 3.5-5 mEq/L. Serum potassium concentrations, however, are not necessarily accurate indications of cellular potassium concentrations, as intracellular potassium accounts for 98% of total body amount. Potassium is excreted mainly by the kidneys. Normally about 80-90% of the potassium intake is excreted in the urine, the remainder in the stools and to a small extent, in the perspiration.

Potassium depletion may occur whenever the rate of loss exceeds the rate of intake. Causes of hypokalemia include: inadequate intake, diuretic therapy, diabetic ketoacidosis, metabolic alkalosis, potassium-losing nephropathy, severe diarrhea, prolonged vomiting, drainage of gastrointestinal fluids, hyperaldosteronism, hepatic cirrhosis with ascites, Bartter syndrome and long-term corticosteroid therapy. Potassium deficiency may cause vomiting, abdominal distention, malaise, myalgia, paralytic ileus, acute muscular weakness, paralysis, paresthesia, polydipsia and an inability to concentrate urine, cardiac arrhythmias, and coma. Hypokalemia may also increase the toxicity of digoxin. Severe potassium depletion (<2.5 mEq/L) may result in elevation of serum creatinine phosphokinase, aldolase, and aspartate aminotransferase levels. Rhabdomyolysis may ensue when the serum potassium concentration falls below 2.0 mEq/L.

Chronic potassium depletion can lead to decreased glomerular filtration rate, renal blood flow, disturbance in tubular sodium handling, impairment of the urinary concentrating ability with polydipsia, and ADH-resistant nephrogenic diabetes insipidus. Reversible pathologic changes include renal hypertrophy and epithelial vacuolization of the proximal convoluted tubule. However, interstitial scarring and tubular atrophy have been reported with prolonged potassium depletion.

10.2 Pharmacodynamics

In vivo studies performed were designed to evaluate the pharmacodynamics of concentrated potassium chloride administration to critically ill patients, pediatric cardiac surgical patients and

cardiopulmonary bypass patients. According to Kruse and Carlson (1990), a positive correlation between the change in serum potassium level and the total dose administered was shown; however, there was only a modest linear correlation between differing hourly rates of potassium administration and change in serum potassium. An average increase in serum potassium level of 0.25 mmol/L per 20 mEq infusion was observed. There was not a clear relationship between changes in potassium and serum creatinine level.

The dose-response curve observed by Schaber et al. had a very low coefficient of determination. Eighty-seven percent of responses were an increase in serum potassium. The variability in response to a given dose was expected due to the complex interaction of the physiologic variables involved such as: the dose administered, arterial pH, pre-infusion serum potassium concentration, and serum bicarbonate concentration. A preinfusion serum potassium less than or equal to 3.5 mEq/L was associated with a change in serum potassium of 0.79 ± 0.23 mEq/kg. Patients with a preinfusion serum potassium less than 3.5 mEq/L received a slightly greater potassium dose than those with a higher preinfusion serum concentration. If the preinfusion serum potassium was greater than 3.5 mEq/L, the change in serum potassium was 0.51 ± 0.48 mEq/L.

Manning et al. (1982) observed that there was only a modest linear correlation between differing hourly rates of potassium administration and change in serum potassium. The mean change in serum potassium after 33.0 mmol of potassium chloride was 0.40 ± 0.42 mmol/L.

Table 4: Dose Response Data

Study Author	Pre-infusion Serum [K+]	Mean Change in Serum Potassium
Kruse and Carlson, 1990	3.22 mmol/L	0.25 mmol/L for each 20 mEq administered
Manning et al. 1982	3.6 ± 0.28 mmol/L	0.40 ± 0.45 mmol/L after administration of 33.0 mEq
Schaber et al. 1985	≤ 3.5 mEq/L	0.79 ± 0.44 mEq/L after administration of 0.78 ± 0.27 mEq/kg
	≥ 3.5 mEq/L	0.51 ± 0.48 mmol/L after administration of 0.69 ± 0.19 mEq/kg

10.3 Pharmacokinetics

Distribution:

Potassium first enters the extracellular fluid and is then actively transported into the cells where its concentration is up to 40 times that outside the cell. According to Kruse et al. (1994), the kinetic behaviour of potassium demonstrated a maximum plasma concentration at the end of the infusion. This maximum concentration decreased rapidly post-infusion and stabilized.

Manning et al. (1982) reported no significant or consistent changes that would indicate a distribution phase.

Elimination

Potassium is excreted mainly by the kidneys. The cation is filtered by the glomeruli, reabsorbed in the proximal tubule, and secreted in the distal tubule, the site of sodium-potassium exchange. Tubular

secretion of potassium is also influenced by chloride ion concentration, hydrogen ion exchange, acid-base equilibrium, and adrenal hormones. Surgery and/or tissue injury result in increased urinary excretion of potassium which may continue for several days. Small amounts of potassium may be excreted via the skin and intestinal tract, but most of the potassium excreted into the intestine is later reabsorbed.

Manning et al. (1982) reported that in postoperative cardiopulmonary bypass patients who were administered intermittent concentrated potassium chloride, a mean potassium intake of 37.4 ± 4.7 mmols resulted in a mean urine potassium excretion of 29.4 ± 19 mmols.

11 STORAGE, STABILITY AND DISPOSAL

Store at room temperature (15° to 25° C).

12 SPECIAL HANDLING INSTRUCTIONS

The ready to use VIAFLEX Plus plastic container is fabricated from a specially formulated polyvinyl chloride. Exposure to temperatures above 25°C 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.

PART II: SCIENTIFIC INFORMATION

13 PHARMACEUTICAL INFORMATION

Drug Substance

Proper name: Potassium chloride, USP

Chemical name: Potassium chloride

Molecular formula and molecular mass: KCl; 74.55

Physicochemical properties: Potassium Chloride USP is a white crystalline powder having a melting point of 770 °C. It is freely soluble in water with a pH range of 4.0-8.0 at 25 °C.

14 CLINICAL TRIALS

This information is not available for this drug product.

15 MICROBIOLOGY

No microbiological information is required for this drug product.

16 NON-CLINICAL TOXICOLOGY

General Toxicology:

The potential toxic side effects of potassium chloride have been characterized through extensive clinical use for many years. Potassium chloride is a well-characterized drug. The medical literature documents the use of concentrated potassium chloride injection and no occurrence of unusual side effects has been noted when proper administration procedures are followed.

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Potassium Chloride Injection

Sterile Injection

Potassium ion (K^+)

10 mEq/50mL, 20 mEq/50mL, 10 mEq/100mL, 20 mEq/100mL, 40mEq/100mL

Electrolyte Replenisher

Read this carefully before you start taking Potassium Chloride Injection and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Potassium Chloride Injection.

Serious Warnings and Precautions

Potassium Chloride Injection must be given to you with extreme caution if you have too much potassium in your system or you are more sensitive to serum potassium levels. Some examples of conditions that would put you at risk include muscle disorders such as potassium-aggravated skeletal muscle channelopathies (e.g., hyperkalemic periodic paralysis, paramyotonia congenita, and potassium-aggravated myotonia/paramyotonia).

Potassium Chloride Injection will be administered with caution to you if you are at risk of experiencing:

- hyperosmolality (high concentration of salts in the blood)
- acidosis (too much acid in the blood)
- undergo correction of alkalosis (conditions associated with a shift of potassium from intracellular to extracellular space)
- if you are receiving (or recently received) treatment with agents or products that can cause you to have too much potassium in your system

Your doctor will monitor your condition.

What is Potassium Chloride Injection used for?

Potassium Chloride Injection is administered by a Healthcare Professional to treat potassium deficiency. This means that your body does not have the blood level of potassium that it needs to work properly.

How does Potassium Chloride Injection work?

Potassium Chloride Injection works by adding potassium to your body.

What are the ingredients in Potassium Chloride Injection?

Medicinal ingredients: Potassium Chloride

Non-medicinal ingredients: Water for Injection.

Potassium Chloride Injection comes in the following dosage forms:

Potassium Chloride Injection comes as a sterile solution for intravenous administration, available in the following strengths and volumes: Potassium ion (K+) 10 mEq/50mL, 10 mEq/100mL, 20 mEq/50mL, 20 mEq/100mL, 40 mEq/100mL.

Do not use Potassium Chloride Injection if:

- you have a hypersensitivity to potassium or to any component of the container (plastic; polyvinyl chloride)
- you already have too much potassium in your body (hyperkalemia)
- you have kidney (renal) impairment
- you have untreated Addison's disease (a condition in which your adrenal glands do not make enough of certain hormones)
- you have irregular heart rhythm (ventricular fibrillation)
- you have a genetic condition of the adrenal gland (salt-losing adrenal hyperplasia)
- you have extensive tissue damage such as severe burns, acute dehydration and heat cramps
- you have increased sensitivity to potassium administration
- you have an overactive adrenal gland (hyperadrenalism associated with adrenogenital syndrome)
- you have abnormal heart rhythm while taking digitalis that leads to heart block (digitalis induced second and third degree heart block)

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Potassium Chloride Injection. Talk about any health conditions or problems you may have, including if you:

- Have heart problems, such as congestive heart failure or problems with the rate or rhythm of your heartbeat
- Have kidney problems
- Have Diabetes
- Have problems with your adrenal gland (e.g. Addison's disease)
- are pregnant
- are breastfeeding an infant

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Potassium Chloride Injection:

- Diuretics that may prevent loss of potassium, such as amiloride, spironolactone, triamterene
- Medications used to treat high blood pressure such as Angiotensin Converting Enzyme (ACE) inhibitors

How to take Potassium Chloride Injection:

- Potassium Chloride Injection will be given to you by a healthcare professional in a healthcare setting.

Usual dose:

The appropriate dose is selected by the Health Care Professional and is administered through a vein.

Overdose:

Symptoms of overdose include: Confusion, Nausea, Vomiting, Abdominal pain, Weakness, Numbness in hands or feet, Difficulty moving or breathing, Change in heartrate or heart rhythm.

If you think you, or a person you are caring for, have taken too much Potassium Chloride Injection, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss your scheduled infusion, contact your doctor or nurse as soon as possible to schedule your next treatment.

What are possible side effects from using Potassium Chloride Injection?

These are not all the possible side effects you may have when taking Potassium Chloride Injection. If you experience any side effects not listed here, tell your healthcare professional.

The side effects reported with Potassium Chloride Injection may be a result of how the product has been given to you (such as pain or infection at the infusion site, fever). Most often, the side effects that occur are a result of your body responding to the increased levels of potassium in your system.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Diarrhea		√	
Administration Site Conditions: Pain, burning and/or swelling at the injection site.		√	
Allergic Reaction: rash or swelling		√	
Hyperkalemia (too much potassium in your system): Confusion, Nausea, Vomiting, Abdominal pain, Weakness, Numbness in hands or feet, Difficulty moving or breathing,		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Change in heartrate or heart rhythm.			

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store at room temperature (15° C to 25° C).

Keep out of reach and sight of children.

If you want more information about Potassium Chloride Injection:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html; the manufacturer's website www. baxter.ca, or by calling 1-888-719-9955.

This leaflet was prepared by:

Baxter Corporation.

Mississauga, ON L5N 0C2.

Last Revised: January 12, 2022