PRODUCT MONOGRAPH

INCLUDING PATIENT MEDICATION INFORMATION

POTASSIUM CHLORIDE FOR INJECTION CONCENTRATE USP

Sterile Solution, Potassium ion (K^+), 500 mEq / 250 mL (2 mEq / mL)

USP

Electrolyte Replenisher

COMPOUNDING ONLY, NOT FOR DIRECT INFUSION

Manufactured by:

B|BRAUN

B. Braun Medical Inc.
824 Twelfth Avenue
Bethlehem, PA 18018-3524 USA

Imported by:
B. Braun of Canada, Ltd.
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RECENT MAJOR LABEL CHANGES

Section 3, Serious Warnings and Precautions Box	03/2023
Section 7, Warnings and Precautions	03/2023

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

PART I: HEALTH PROFESSIONAL INFORMATION

1 INDICATIONS

Potassium Chloride for Injection Concentrate USP 500 mEq / 250 mL (2 mEq / mL) is indicated for:

- Treatment of potassium deficiency states when oral replacement is not feasible.

This is a concentrated solution which is intended for use in a pharmacy admixture service and is restricted to the preparation of admixtures for intravenous infusion.

1.1 Pediatrics

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

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 for Injection Concentrate USP 500 mEq / 250 mL (2 mEq / mL) 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, STRENGTH, COMPOSITION AND PACKAGING.
- Diseases where high potassium levels may be encountered
- In patients with:
    - Hyperkalemia
    - Renal failure
    - Conditions in which potassium retention is present
    - Conditions where additives of potassium and chloride could be clinically detrimental

3 SERIOUS WARNINGS AND PRECAUTIONS BOX

Serious Warnings and Precautions

- PHARMACY BULK PACKAGE, NOT FOR DIRECT INFUSION, FATAL IF GIVEN BY DIRECT INFUSION (see 4 DOSAGE AND ADMINISTRATION)
- **Strongly Hypertonic Solution.** Must be properly diluted and thoroughly mixed before injection (see 7 WARNINGS AND PRECAUTIONS)
- Potentially Fatal Cardiac Adverse Reactions with Undiluted Intravenous Administration (see 7 WARNINGS AND PRECAUTIONS)
- This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired (see 7 WARNINGS AND PRECAUTIONS)

4 DOSAGE AND ADMINISTRATION

4.1 Dosing Considerations

- **Not for direct patient injection.**
- Potassium Chloride for Injection Concentrate USP, Pharmacy Bulk Package is for preparation of intravenous admixtures only and must be diluted before administration.
- Care must be taken to ensure there is complete mixing of the potassium chloride with the large volume fluid, particularly if soft or bag type containers are used.

4.2 Recommended Dose and Dosage Adjustment

Dosage and rate of administration are to be directed by the physician and are dependent upon the specific conditions of each patient (e.g., age, weight, clinical condition of the patient and laboratory determinations). Frequent laboratory determinations and clinical evaluation are essential to monitor changes in electrolyte concentrations, and fluid and electrolyte balance during prolonged parenteral therapy.

If the serum potassium level is greater than 2.5 mEq / liter, potassium can be given at a rate not to exceed 10 mEq / hour and in a concentration of up to 40 mEq / liter. The 24 hour total dose should not exceed 200 mEq.

If urgent treatment is indicated (serum potassium level less than 2.0 mEq / liter and electrocardiographic changes and/or muscle paralysis), potassium chloride may be infused very cautiously at a rate of up to 40 mEq / hour. In such cases, continuous cardiac monitoring is essential. As much as 400 mEq may be administered in a 24 hour period. In critical conditions, potassium chloride may be administered in saline (unless contraindicated) rather than in dextrose containing fluids, as dextrose may lower serum potassium levels.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

Health Canada has not authorized an indication for pediatric use (see 1.1 Pediatrics).

4.4 Administration

Warning: Not for direct infusion. For preparation of admixtures for intravenous infusion.

Potassium Chloride for Injection Concentrate USP is a sterile, nonpyrogenic, concentrated solution of Potassium Chloride USP in Water for Injection USP to be administered by intravenous infusion only after dilution in a larger volume of fluid. No bacteriostatic or antimicrobial agent has been added.

A pharmacy bulk package is a container of a sterile preparation for parenteral use that contains many single doses. The contents are intended for use in a pharmacy admixture service and are restricted to the preparation of admixtures for intravenous infusion.

Directions for Use of Pharmacy Bulk Package in B. Braun Excel Container with Blocked Medication Port.

The Pharmacy Bulk Package is for use in a Pharmacy Admixture Service only. Use of this product is restricted to a suitable work area, such as a laminar flow hood (or an equivalent clean air compounding area).

Additives should not be made to Pharmacy Bulk Packages.

Caution: Do not use plastic containers in series connection.

To Open

Tear overwrap down at notch and remove solution container. Check for minute leaks by squeezing solution container firmly. If leaks are found, discard solution as sterility may be impaired.

NOTE: Before use, perform the following checks:

Inspect each container. Read the label. Ensure solution is the one ordered and is within the expiration date.

Invert container and carefully inspect the solution in good light for cloudiness, haze, or particulate matter. Any container which is suspect should not be used.

Use only if solution is clear and container and seals are intact.

Preparation for Admixing

1. Remove plastic protector from sterile set port at bottom of container.
2. Attach suitable transfer device or compounding set. Refer to complete directions accompanying device.

Do Not Add Medication

Transfer individual dose(s) to appropriate intravenous infusion solutions. Use of a syringe with needle is not recommended. Multiple entries increase the potential of microbial and particulate contamination. The container closure may be penetrated only one time, utilizing a suitable sterile dispensing set which allows measured dispensing of the contents.

For Pharmacy Bulk Packages

- The Pharmacy Bulk Package is to be used only in a suitable work area such as a laminar air flow hood (or an equivalent clean air compounding area).
- For compounding only. Do not use for direct infusion.
- Do not use/penetrate blocked port.

- Suspend container.
- Attach suitable transfer device or compounding set. Refer to complete directions accompanying device.
- Hang bag on suitable fixture.
- Once container closure has been penetrated, withdrawal of contents should be completed within 4 hours. Discard any unused portion.

Important Admixing Instructions

- The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for intravenous infusion.
- Additives may be incompatible with the fluid withdrawn from this container. Consult with pharmacist.
- When compounding admixtures, use aseptic technique, mix thoroughly and discard unused portion.
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration (See 7 WARNINGS AND PRECAUTIONS, General).

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 of fluid overload during parenteral therapy, re-evaluate the patient's condition and institute appropriate corrective treatment.

In the event of overdosage with potassium-containing solutions, discontinue the infusion immediately and institute corrective therapy to reduce serum potassium levels.

Treatment of hyperkalemia includes the following:

1. Dextrose Injection USP, 10% or 25%, containing 10 units of crystalline insulin per 20 grams of dextrose administered intravenously, 300 to 500 mL per hour.

2. Absorption and exchange of potassium using sodium or ammonium cycle cation exchange resin, orally and as retention enema.
3. Hemodialysis and peritoneal dialysis. The use of potassium-containing foods or medications must be eliminated. However, in cases of digitalization, too rapid a lowering of plasma potassium concentration can cause digitalis toxicity.

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

6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

Table 1: Dosage Forms, Strengths, Composition and Packaging

Route of Administration	Dosage Form / Strength / Composition	Non-medicinal Ingredients
PHARMACY BULK PACKAGE **NOT FOR DIRECT INFUSION** **Must Be Diluted Prior To Injection** **For Intravenous Infusion Only**	Sterile solution of: Potassium ion (K^+) 500 mEq / 250 mL (2 mEq / mL)	Water for Injection USP

Potassium Chloride for Injection Concentrate USP, 500 mEq / 250 mL (2 mEq / mL) is supplied as sterile and nonpyrogenic solution in 250 mL Excel containers, Pharmacy Bulk Packages, packaged 24 per case.

Excel container not made with natural rubber latex, PVC or DEHP.

The plastic container is made from a multi-layered film specifically developed for parenteral drugs. 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 admixing. The container is overwrapped to provide protection from the physical environment and to give an additional moisture barrier when necessary.

The closure system has two ports; the one for the suitable transfer device or compounding set has a tamper evident plastic protector and the other is a non-accessible blocked port. Refer to the Directions for Use of the container.

The container closure may be penetrated only one time, utilizing a suitable sterile dispensing set which allows measured dispensing of the contents.

The withdrawal of container contents should be accomplished without delay using aseptic technique. Discard container within 4 hours of entering closure.

7 WARNINGS AND PRECAUTIONS

General

This concentrated solution of potassium chloride is for use in intravenous admixtures only and must not be used undiluted for direct patient injection. Direct patient injection of potassium chloride at this concentration may be instantaneously fatal. Fatal cardiac arrhythmia and cardiac arrest have occurred when potassium chloride was administered in an undiluted form.

To avoid potassium intoxication, do not infuse these solutions rapidly.

The administration of intravenous solutions can cause fluid and/or solute overload resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentration. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentration.

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid-base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation. Significant deviations from normal concentrations may require the use of additional electrolyte supplements, or the use of electrolyte-free dextrose solutions to which individualized electrolyte supplements may be added.

Potassium therapy should be guided primarily by serial electrocardiograms, especially in patients receiving digitalis. Serum potassium levels are not necessarily indicative of tissue potassium levels. Solutions containing potassium should be used with caution in the presence of cardiac disease, particularly in the presence of renal disease, and in such instances, cardiac monitoring is recommended.

Solutions containing potassium in a greater concentration than 40 mEq / liter may result in significant irritation to peripheral or central veins.

For peripheral administration of solutions containing potassium, slowly infuse the solution through a small bore needle, placed well within the lumen of a large vein. Carefully avoid infiltration.

Solutions containing dextrose should be used with caution in patients with overt or known subclinical diabetes mellitus, or carbohydrate intolerance for any reason.

If the administration is controlled by a pumping device, care must be taken to discontinue pumping action before the container runs dry or air embolism may result.

To minimize the risk of possible incompatibilities arising from mixing this solution with other additives that may be prescribed, the final infusate should be inspected for cloudiness or precipitation immediately after mixing, prior to administration, and periodically during administration.

Use only if solution is clear and container and seals are intact. Discard the container no later than 4 hours after initial closure puncture.

Cardiovascular

The signs and symptoms of potassium intoxication include hypotension, cardiac arrhythmias, heart block, electrocardiographic abnormalities and cardiac arrest.

Renal

WARNING: This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.

Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 mcg / kg / day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

To avoid potassium intoxication, do not infuse these solutions rapidly. In patients with renal insufficiency, administration of potassium chloride may cause potassium intoxication and life-threatening hyperkalemia.

In patients with diminished renal function, administration of solutions containing potassium ions may result in potassium retention.

The drug product contains no more than 25 mcg / L of aluminum.

Reproductive Health: Female and Male Potential

- **Teratogenic Risk**

  See 7.1.1 Pregnant Women

7.1 Special Populations

7.1.1 Pregnant Women

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

7.1.2 Breast-feeding

It is unknown if Potassium Chloride for Injection Concentrate USP is excreted in human milk. Because many drugs are excreted in human milk precaution should be exercised.

7.1.3 Pediatrics

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

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

Reactions which may occur because of the potassium-containing solutions or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection or extravasation, hypervolemia, and hyperkalemia.

Too rapid infusion of hypertonic solutions may cause local pain and, rarely, vein irritation. Rate of administration should be adjusted according to tolerance.

Reactions reported with the use of potassium-containing solutions include nausea, vomiting, abdominal pain and diarrhea. The signs and symptoms of potassium intoxication include paresthesias of the extremities, areflexia, muscular or respiratory paralysis, mental confusion, weakness, hypotension, cardiac arrhythmias, heart block, electrocardiographic abnormalities and cardiac arrest. Potassium deficits result in disruption of neuromuscular function, and intestinal ileus and dilatation.

If infused in large amounts, chloride ions may cause a loss of bicarbonate ions, resulting in an acidifying effect.

Potassium-containing solutions are intrinsically irritating to tissues. Therefore, extreme care should be taken to avoid perivascular infiltration. Local tissue necrosis and subsequent sloughing may result if extravasation occurs. Chemical phlebitis and venospasm have also been reported.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

9 DRUG INTERACTIONS

9.2 Drug Interactions Overview

To minimize the risk of possible incompatibilities arising from mixing this solution with other additives that may be prescribed, the final infusate should be inspected for cloudiness or precipitation immediately after mixing, prior to administration, and periodically during administration.

9.4 Drug-Drug Interactions

To minimize the risk of possible incompatibilities arising from mixing this solution with other additives that may be prescribed, the final infusate should be inspected for cloudiness or precipitation immediately after mixing, prior to administration, and periodically during administration.

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

Normally about 80 to 90% of the potassium intake is excreted in the urine, the remainder in the stools and to a small extent, in the perspiration. The kidney does not conserve potassium well so that during fasting, or in patients on a potassium-free diet, potassium loss from the body continues resulting in potassium depletion. A deficiency of either potassium or chloride will lead to a deficit of the other.

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.[1]

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 pre-infusion 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 pre-infusion serum potassium less than 3.5 mEq / L received a slightly greater potassium dose than those with a higher pre-infusion serum concentration. If the pre-infusion serum potassium was greater than 3.5 mEq / L, the change in serum potassium was 0.51 ± 0.48 mEq / L.[2]

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.[3]

Dose Response Data

Study Author	Pre-infusion Serum [K^+]	Mean Change in Serum Potassium
Kruse and Carlson, 1990 [1]	3.22 mmol / L	0.25 mmol / L for each 20 mEq administered
Manning et al. 1982 [2]	3.6 ± 0.28 mmol / L	0.40 ± 0.45 mmol / L after administration of 33.0 mEq
Schaber et al. 1985 [3]	≤ 3.5 mEq / L ≥ 3.5 mEq / L	0.79 ± 0.44 mEq / L after administration of 0.78 ± 0.27 mEq / kg 0.51 ± 0.48 mmol / L after administration of 0.69 ± 0.19 mEq / kg

[1] Kruse JA, Carlson RW. Rapid correction of hypokalemia using concentrated intravenous potassium chloride infusions. Archs Intl Med. 1990;150: 613-7.

[2] Schaber DE, Uden DL, Stone FM et al. Intravenous KCl: Supplementation in pediatric cardiac surgical patients. Ped Cardiol. 1985; 6: 25-8.

[3] Manning SM, Angaran DM, Arom KV et al. Intermittent intravenous potassium therapy in cardiopulmonary bypass patients. Clin Pharm. 1982;1:234-8.

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 postinfusion 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

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. Protect from freezing. Store at 15° to 25°C. Discard any unused portion.

12 SPECIAL HANDLING INSTRUCTIONS

Receiving pharmacies should create additional labels and affix them on each side of the container. The label should contain the same information as the label provided by the manufacturer.

PART II: SCIENTIFIC INFORMATION

13 PHARMACEUTICAL INFORMATION

Drug Substance

Proper name: Potassium Chloride for Injection Concentrate

Chemical name: Potassium chloride

Molecular formula and molecular mass: KCl; 74.55 g / mol

Physicochemical properties: pH: 5.4 (4.0-8.0); Calculated Osmolarity: 4000 mOsmol / liter

Each 100 mL of Potassium Chloride contains: Potassium Chloride USP 14.9 g; Water for Injection USP qs

Concentration of Electrolytes (mEq / mL): Potassium 2; Chloride 2

14 CLINICAL TRIALS

Not available.

15 MICROBIOLOGY

No microbiological information is required for this drug product.

16 NON-CLINICAL TOXICOLOGY

No long-term animal studies have been performed to evaluate carcinogenic or mutagenic potential or whether Potassium Chloride for Injection Concentrate USP affects fertility in males or females.

17 SUPPORTING PRODUCT MONOGRAPHS

1. Potassium Chloride Injection, Sterile Solution, 10 mEq / 50mL, 20 mEq / 50mL, 10 mEq / 100mL, 20 mEq / 100mL, and 40 mEq / 100mL, submission control number 157615, Product Monograph, Baxter Corporation, OCT 25 2012.

2. Potassium Chloride for Injection Concentrate, USP, Sterile Solution, 20 mEq / 10mL and 40 mEq / 20mL, Product Monograph, Hospira Healthcare Corporation, OCT 2004.

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

POTASSIUM CHLORIDE FOR INJECTION CONCENTRATE USP

Potassium Chloride for Injection Concentrate

Read this carefully before you start taking **Potassium Chloride for Injection Concentrate USP** 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 for Injection Concentrate USP**.

Serious Warnings and Precautions

- This drug must be:
  - properly diluted and thoroughly mixed by your doctor, nurse or pharmacy before use.
  - administered with caution and under the supervision of your doctor or nurse.
- Direct injection of potassium chloride at this concentration may be instantaneously fatal.
- This drug contains aluminum that may be toxic. It may reach toxic levels with long term use if you have kidney problems.

What is Potassium Chloride for Injection Concentrate USP used for?

- It is used to treat low levels of potassium. It is used when you are not able to take potassium by mouth.

How does Potassium Chloride for Injection Concentrate USP work?

Having a normal level of potassium in your blood is important. It helps your cells, heart, muscles and nerves work properly.

If you are on a potassium-free diet or fasting, you may have a lower than normal level of potassium in your blood. This drug will help raise your potassium levels.

What are the ingredients in Potassium Chloride for Injection Concentrate USP?

Medicinal ingredients: Potassium Chloride

Non-medicinal ingredients: Water for Injection USP.

Potassium Chloride for Injection Concentrate USP comes in the following dosage forms:

Concentrated solution (sterile): 500 mEq / 250 mL (2 mEq / mL)

Do not use Potassium Chloride for Injection Concentrate USP if:

- Are Allergic to this drug or to any ingredient in the formulation or the components of the container.
- Have high levels of potassium in your blood
- Have Kidney failure
- Have Addison's disease (a disease of the adrenal gland) and are not being treated for it
- Have a genetic condition of the adrenal glands
- Have tissue damage
- Have a condition in which potassium is not removed from the body
- Have a condition where you are taking extra potassium and chloride

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

- Have diabetes or carbohydrate intolerance
- Have Heart disease
- Have Kidney problems
- Have Problems with your adrenal glands
- Are Pregnant, or planning on becoming pregnant. It is not known if the drug can cause harm to your unborn baby
- Are Breastfeeding. It is not known if this drug can pass through your breast milk to your baby

Other warnings you should know about:

Laboratory tests: in order to monitor you, your doctor may perform laboratory tests while you are on this treatment.

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 for Injection Concentrate USP:

- Medications that increase urination (potassium sparing diuretics).
- Medications to treat high blood pressure (ACE inhibitors or angiotensin II receptor antagonists).
- Anticholinergics.

How to take Potassium Chloride for Injection Concentrate USP:

- This is not a medication that you can use yourself.
- It will be given into your vein by slow infusion (drip) by your doctor or nurse.
- The medication will be mixed with other fluids by the pharmacy first before your doctor or nurse gives it to you.

Usual dose:

Your doctor will decide what dose of medication you will receive and for how long. This depends on your medical condition and other factors, such as your weight and the results of your blood tests.

Overdose:

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

What are possible side effects from using Potassium Chloride for Injection Concentrate USP?

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

- Nausea
- Vomiting
- Stomach pain
- Diarrhea
- Fever
- Infection at the injection site
- Formation of a blood clot
- Inflammation of the vein
- Pain at the injection site
- Too much fluid in the blood
- High levels of potassium (hyperkalemia)
- Vein irritation
- Confusion
- Restlessness
- Weakness
- Tingling or prickling sensation (paresthesias) or an inability to move your hands or feet (paralysis)
- Irregular heart beat
- Low blood pressure

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/adverse-reaction-reporting.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.

If you want more information about Potassium Chloride for Injection Concentrate USP:

- 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), or by calling 1-800-227-2862.

This leaflet was prepared by B. Braun Medical Inc.

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