POTASSIUM CHLORIDE FOR INJECTION CONCENTRATE USP

Electrolyte Replenisher

FOR INTRAVENOUS USE ONLY AFTER DILUTION AND THOROUGH MIXING IN LARGER VOLUME OF FLUID

Plastic Vial

INDICATIONS AND USAGE

Potassium Chloride for Injection Concentrate USP is indicated in the treatment of potassium deficiency states when oral replacement therapy is not feasible.

Potassium Chloride for Injection Concentrate USP (appropriately diluted) is a parenteral fluid and electrolyte replenisher.

CONTRAINDICATIONS

Potassium Chloride for Injection Concentrate USP is contraindicated in diseases where high potassium levels may be encountered, and in patients with hyperkalemia, renal failure and in conditions in which potassium retention is present.

WARNINGS

Potentially Fatal Cardiac Adverse Reactions with Undiluted Intravenous Administration
Direct patient injection of potassium chloride at this concentration may be instantaneously fatal. Potassium Chloride for Injection Concentrate must be diluted before administration. Fatal cardiac arrhythmia and cardiac arrest have occurred when potassium chloride was administered in an undiluted form.

Solutions which contain potassium ions should be used with great care, if at all, in patients with hyperkalemia, severe renal failure and in conditions in which potassium retention is present.

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

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

The intravenous administration of these solutions (after dilution) can cause fluid and/or solute overloading 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 of administered parenteral solutions.

The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of such solutions.

PRECAUTIONS

General

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 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.

Care should be exercised to ensure that the needle (or catheter) is well within the lumen of the vein and that extravasation does not occur. See **ADVERSE REACTIONS**.

Drug Interactions

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

Usage in Pregnancy

It is 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.

ADVERSE REACTIONS

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, hypervolemia, and hyperkalemia.

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.

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.

Should perivascular infiltration occur, intravenous administration at that site should be discontinued at once. Local infiltration of the affected area with 1% procaine hydrochloride, to which hyaluronidase may be added, will often reduce venospasm and dilute the potassium remaining in the tissues locally. Local application of heat may also be helpful.

Too rapid infusion of hypertonic solutions may cause local pain and, rarely, vein irritation. Rate of administration should be adjusted according to tolerance. Use of the largest peripheral vein and a small bore needle is recommended.

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.

OVERDOSAGE

In the event of fluid overload during parenteral therapy, reevaluate 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, at a rate of 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.

DOSAGE AND ADMINISTRATION

POTASSIUM CHLORIDE FOR INJECTION CONCENTRATE USP 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.

The dose and rate of injection are dependent upon the individual needs of each patient.

If the serum potassium level is greater than 2.5 mEq/liter, potassium chloride may be infused very cautiously at a rate not to exceed 10 mEq/hour in a concentration of up to 40 mEq/liter. The total 24-hour dose should not exceed 200 mEq.

If urgent treatment is indicated (serum potassium level less than 2.0 mEq/liter with electrocardiographic changes or paralysis), potassium chloride may be infused very cautiously at a rate of 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 states, potassium chloride may be administered in saline (unless sodium chloride is contraindicated), rather than in dextrose solutions, as the infusion of dextrose fluids may lower serum potassium levels.

HOW SUPPLIED

Potassium Chloride for Injection Concentrate USP electrolyte replenishers are sterile, nonpyrogenic, **concentrated** solutions of potassium chloride, in water for injection USP, administered by intravenous infusion only after dilution in a larger volume of fluid.

Each millilitre contains potassium chloride 149 mg; may contain hydrochloric acid for pH adjustment; the pH is approximately 4.5 (4.1 to 6.0). The solution provides 2 mEq (2 mmol)/mL each of K+ and Cl- and has an osmolarity of 4000 mOsm/L.

Potassium chloride should only be used in conjunction with a suitable pharmacy-directed admixture program; the solution should be used within 24 hours; any unused portion should be discarded.

The solution contains no bacteriostat, antimicrobial agent and is intended only for single-use infusion (after dilution). When smaller doses are required, the unused portion should be discarded.

Potassium Chloride for Injection Concentrate USP electrolyte replenishers are supplied in single-use 20 and 40 mEq plastic fliptop vials as follows:

List No	Concentration
06651	20 mEq/10 mL
06653	40 mEq/20 mL

Exposure of pharmaceutical products to heat should be minimized. **Protect from freezing and excessive heat**. Store between 20 and 25°C (see "Controlled Room Temperature" in USP). Brief exposure up to 40°C does not adversely affect the product.

Parenteral drug products should be inspected visually for particulate matter and discolouration, whenever solution and container permit.

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Pfizer Canada ULC
Kirkland, Québec H9J 2M5