

Potassium Chloride for Injection Concentrate USP

CHLORPOT™

Each ml contains:

Potassium Chloride IP	150 mg
Water for injection IP	q.s.

DESCRIPTION:

Potassium Chloride is used in prevention and treatment of potassium deficiency when oral replacement therapy is not feasible. Potassium Chloride is designated by potassium; chloride. It has a molecular weight 74.6 g/mol and its molecular formula is KCl.

THERAPEUTIC INDICATIONS:

For use in patients requiring supplemental potassium therapy.

POSOLGY AND METHOD OF ADMINISTRATION

Posology:

The goal of potassium replacement therapy is to elevate the plasma concentration of the ion to within the normal range.

Dose per hour: The maximal rate of intravenous infusion is 20mmol/hour.

Dose per day: Since the normal dietary intake of potassium is 50 to 100mmol daily, it is rare that a larger amount is required during potassium replacement therapy.

Method of administration:

Intravenous, after dilution.

Before administering Sterile Potassium Chloride Concentrate:

1) This solution must be diluted with not less than 50 times its volume of water for injection or another suitable diluent.

2) The solution should be carefully mixed with the infusion fluid.

During administration:

1) The diluted injection should be administered by slow intravenous infusion at a maximal rate of 20mmol of potassium per hour.

2) The ECG should be monitored continuously.

CONTRAINDICATIONS:

- Hypersensitivity to the active substance or to any of the excipients
- Sterile Potassium Chloride Concentrate should never be used undiluted.
- Hyperkalaemia (plasma-potassium concentration above 5 mmol/litre).
- Hyperchloraemia,
- Impaired renal function with oliguria, anuria or azotaemia
- Addison's disease,
- Acute dehydration
- Heat cramps

SPECIAL WARNINGS AND PRECAUTIONS FOR USE:

Administration – see also section posology and method of administration

- Only use with specialist advice
 - ECG should be used throughout and monitored continuously
 - High concentrations of potassium cause serious cardiotoxicity, so the concentration of the solution should not exceed 3g (40mmol)/L and the diluted solution given slowly (maximal rate 20mmol/L)
- Initially do not use with glucose infusions – glucose may further decrease potassium levels.

Other concurrent treatment – also interaction with other medicinal products and other forms of interaction.

- Extreme caution in patients on potassium sparing diuretics and other drugs that may increase potassium
- Glucose infusion – see above Administration

Monitoring

- Continuous ECG monitoring – see above Administration
- Regular potassium levels especially in patients with renal impairment (contraindications)

Underlying conditions – see also section contraindications

- Dehydration must be corrected to ensure adequate urinary output (and potassium excretion)
- Where renal excretion of potassium or cellular uptake deficient – life threatening hyperkalaemia can occur with standard doses Extreme caution with extensive tissue destruction (e.g. burns)
- Extreme caution in cardiac disease

DRUG INTERACTION WITH OTHER MEDICINAL PRODUCTS:

Increased risk of severe hyperkalaemia with the following

- ACE-inhibitors
- Aliskerin
- Angiotensin-II receptor antagonists
- Potassium sparing diuretics such as: amiloride, spironolactone and triamterene and aldosterone antagonists
- Ciclosporin
- Tacrolimus (not topical formulations)

Particularly close monitoring required with these (special warning and precautions for use) and any other medicines or conditions that may increase potassium levels. Further reductions in potassium occurs with glucose infusions – see also section special warning and precaution for use.

FERTILITY, PREGNANCY AND LACTATION:

Potassium chloride should be used during pregnancy or lactation only under the supervision of the prescribing physician if considered essential by the physician

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:

None stated.

UNDESIRABLE EFFECTS

System Organ Class	Adverse events
Metabolism and nutrition disorders	Hyperkalaemia ¹
Nervous system disorders	Paraesthesia ¹ , paralysis ¹
Cardiac disorders	Cardiac arrhythmias ¹ , cardiac arrest ¹
Vascular disorders	Phlebitis ² , hypotension ¹
Musculoskeletal and connective tissue disorders	Muscle weakness ¹
General disorders and administration site conditions	Pain ²

*1 Excessive intake of potassium.

*2 Pain at the injection site and phlebitis may occur during IV administration of solutions containing 30 mmol potassium or more per litre.

OVERDOSE:

Symptoms: Clinical signs and symptoms of potassium overdosage include:

Paraesthesia of the extremities, listlessness, mental confusion, weakness or heaviness of the legs, flaccid paralysis, cold skin, grey pallor, peripheral vascular collapse, fall in blood pressure, cardiac arrhythmias and heart block, due to which patients may deteriorate rapidly.

Extremely high plasma potassium concentrations (8-11 mmol/litre) may cause death from cardiac depression, arrhythmias or arrest.

All drugs containing potassium should be withdrawn and potassium-sparing diuretics discontinued.

Treatment: Serum concentrations may be reduced by infusion of 300 – 500 mls per hour of 10% - 25% glucose solutions containing up to 10 units of insulin for each 20 g of glucose, or by the infusion of sodium bicarbonate solution.

Cardiac arrhythmias or a serum concentration above 6.5 mmol/litre, require immediate attention and may be treated by intravenous injection over 1 – 5 minutes of 10 – 20 ml of 10% Calcium Gluconate Injection B.P. with E.C.G. monitoring. Mild hyperkalaemia may be treated with sodium polystyrene sulphonate, a cation-exchange resin administered by mouth or as an enema. If the above measures fail, haemodialysis or peritoneal dialysis may be required.

Monitoring

- Measure urea, electrolytes and creatinine
- Monitor potassium levels regularly (2 to 3 hourly if raised)
- Continuous 12 lead ECG
- Observe asymptomatic patients for at least 6 hours

PHARMACOLOGICAL PROPERTIES:

Pharmacotherapeutic group: Electrolyte Solution

ATC code: B05XA01

Pharmacodynamic properties:

Active ion transport by the sodium-potassium ATPase carrier maintains a high gradient of potassium across the plasma membrane. Intracellular concentrations of potassium are about 150 mEq per litre while the plasma concentration is in the range of 3.5 to 5 mEq per litre, although there is a modest variation from one cell type to another.

Potassium plays a vital physiological role in maintenance of normal electrical excitability of nerve and muscle. It is also important in the genesis and correction of imbalances of acid-base metabolism.

In acute hypokalaemia, parenteral administration of potassium chloride promptly corrects the deficit in plasma potassium concentration and restores normal physiological function to potassium-dependent systems.

Pharmacokinetic properties:

Absorption: Potassium is an essential dietary constituent and is readily absorbed from the gastro-intestinal tract. Accumulation of potassium by cells occurs via an energy-dependent mechanism that extrudes sodium. Active ion transport systems maintain a high gradient of potassium across the plasma membrane, resulting in plasma concentrations of about 3.5 to 5 mEq per litre and intracellular concentrations of approximately 150 mEq per litre.

Distribution: As a consequence of the large volume of distribution and the rapid response of the kidney, intracellular and extracellular concentrations of potassium are normally maintained within relatively narrow limits. However, when potassium is administered as a drug, the factors that govern the rate and extent of its distribution are of critical importance. Although administration of potassium will not significantly increase the total body content of the ion, it may easily raise the extracellular concentration excessively. Because it is the extracellular concentration of potassium that determines life-threatening toxicity, awareness of the transient concentration achieved in plasma should govern the use of potassium therapy.

Elimination: Potassium is excreted mainly by the kidneys. It is freely filtered at the glomerulus and is mainly absorbed in the proximal tubules, so that by the time the tubular fluid reaches the late distal tubules, it contains less than 10% of the amount of potassium in the original glomerular filtrate. Normally, considerable amounts of potassium are secreted into the distal tubules and secretory transport is extremely important for the control of plasma potassium concentration.

SPECIAL PRECAUTIONS FOR DISPOSAL

Warning: must be diluted before use. Dilute before use with not less than 50 times its volume of diluents. Injection or another suitable diluent. Discard if cloudy or deposit present. Use as directed by the physician. If only part used, discard the remaining solution. Keep out of reach of children.

STORAGE: Do not store above 25°C. Keep in outer carton in order to protect from light.

PRESENTATION:

Primary Packing: 10 ml glass ampoule USP Type-I.

Secondary Packing: Such 5 ampoules are placed in tray, packed in printed monocarton along with package insert.

Mfd. by:

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