

Potassium Chloride

for Injection Concentrate USP (10% w/v)

2683 mOsmol/L (calc) 13.4m Eq per 10ml

For IV use only

Composition:

Each ml contains:

Potassium Chloride USP 10.0% w/v

100mg 1.34m Eq

Water for Injection USP.....q.s.

Pharmacodynamic properties

Potassium is the major cation of intracellular fluid and is essential for maintenance of acid-base balance, isotonicity and the electrodynamic characteristics of the cell. Potassium chloride is used as a source of the potassium cation for treatment or prevention of potassium depletion in patients in whom dietary measures are inadequate. Potassium chloride may also be used cautiously to abolish arrhythmias or cardiac glycoside toxicity precipitated by a loss of potassium.

Pharmacokinetic properties

Potassium chloride is generally readily absorbed from the gastro-intestinal tract. Potassium is excreted mainly by the kidneys; it is secreted in the distal tubules which are also the site of sodium-potassium exchange. The capacity of the kidneys to conserve potassium is poor and urinary excretion of potassium continues even when there is severe depletion. Tubular secretion of potassium is influenced by several factors, including chloride ion concentration, hydrogen ion exchange, acid-base equilibrium and adrenal hormones. Some potassium is excreted in the faeces and small amounts may also be excreted in saliva, sweat, bile and pancreatic juice.

Therapeutic indications:

Potassium Chloride Concentrate 10% is used as a source of the potassium cation for the treatment or prevention of potassium depletion in patients for whom dietary measures or oral medication are inadequate. Potassium salts may also be used cautiously in those taking digoxin where potassium depletion may cause arrhythmias. Potassium Chloride Concentrate 10% must be administered by slow IV, as a dilute solution.

Posology and method of administration:

Adults (including elderly) and Children:

Potassium Chloride Concentrate 10% must be diluted by adding to a large volume intravenous fluid before use. For example, 10 mls diluted with not less than 500 mls 0.9% Sodium Chloride Intravenous Infusion USP, or other suitable diluent, and mixed well.

Dosage depends on the serum ionogram value and the acid-base state. A potassium deficiency is calculated according to the formula:

MMOL Potassium = $KG \times BW \times 0.2 \times 2 \times (4.5 - \text{actual serum potassium (MMOL)})$.

(The extracellular volume is calculated from the body weight in KG $\times$ 0.2).

It is recommended not to exceed 2-3 MMOL potassium per kg body weight in 24 hours.

Contraindications:

Hyperkalaemia, hyperchloraemia, impaired renal function with oliguria, anuria or azotaemia, Addison's disease, acute dehydration and heat cramps.

Special warnings and precautions for use:

Potassium Chloride Concentrate 10% must not be injected undiluted.

Plasma potassium concentration must be measured at regular intervals to avoid the development of hyperkalaemia, especially in patients with renal impairment.

ECG monitoring facilities should be available.

Initial potassium replacement therapy should not involve glucose infusions, because glucose may cause a further decrease in the plasma potassium concentration.

Potassium supplements should be administered with caution in patients with cardiac disease and in patients who are receiving potassium sparing diuretics or other medications which may increase plasma potassium levels.

Interaction with other medicinal products and other forms of interaction

Potassium sparing diuretics:

Potassium supplements should not be administered with potassium sparing diuretics (such as amiloride, spironolactone and triamterene), particularly in patients with impaired renal function. Any patients on this combination require close monitoring in order to diagnose a potential hyperkalaemic condition as soon as possible.

Angiotensin-converting enzyme inhibitors and angiotensin II receptor antagonists:

Patients taking ACE-inhibitors or angiotensin II receptor antagonists, especially those with impaired renal function, should be closely monitored, as the potassium sparing effect in combination with potassium infusion may result in hyperkalaemia.

Ciclosporin:

Concurrent use of ciclosporin may increase the risk of hyperkalaemia.

Glucose Infusion:

Concomitant use of glucose infusions in hypokalaemic patients may cause a further decrease in plasma potassium concentrations.

Pregnancy and lactation

Potassium Chloride Concentrate 10% may be used during pregnancy and lactation under the supervision of the prescribing physician.

Undesirable effects

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

Hyperkalaemia is the most common and serious hazard of potassium therapy.

Overdose

Clinical signs and symptoms of potassium overdose 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. Extremely high plasma potassium concentrations (8-11 MMOL/litre) may cause death from cardiac depression, arrhythmias or arrest.

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. 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.

Storage:

Store below 25°C, protected from light. Preserve in single-dose or in multiple dose container.

Do not allow to freeze.

Keep the medicine out of the reach of children.

Presentation: 10 ml Plastic Ampoule Packed in a carton with insert.

Manufactured in India:

