104/13600435/0911

Directions for Use

B. Braun Melsungen AG · 34209 Melsungen, Germany

Concentrated Sterile solution of 14.9% Potassium Chloride Inj.

The format of this leaflet was determined by the Ministry of Health and its content was checked and approved in November 2010

Composition

10 ml solution contains:

Potassium Chloride	1.49 g

Excipient

Water for Injections

1 ml contains 2 mmol potassium and 2 mmol chloride.

Theoretical osmolarity	3995 mOsm/l
pH	4.5–7.5

Pharmaceutical form

Concentrate for solution for infusion.

Pharmaco-therapeutic group

Electrolyte replacement solutions.

Indications

States of potassium deficiency when oral replacement is not feasible.

Contraindications

Concentrated Sterile Solution containing 14.9% Potassium Chloride must not be administered when there are

- an elevated potassium level (hyperkalaemia)
- an elevated chloride level (hyperchloraemia)
- disorders that are frequently associated with hyperkalaemia such as dehydration, reduced renal excretion, Addison's disease, Adynamia episodica hereditaria (Gamstorp's syndrome), sickle cell anaemia, crush syndrome, heat cramps.

Special precautions for use

Clinical monitoring should include checks of the serum ionogram and the acid-base balance.

Plasma potassium levels are not necessarily indicative of tissue potassium levels.

High plasma concentrations of potassium may cause death through cardiac depression, arrhythmias or arrest.

It must be made absolutely sure that the solution is administered intravenously, because paravenous administration may cause tissue necrosis.

Normal kidney function permits safe potassium therapy. Rapid infusion of an initial hydrating solution (i.e. 5% Glucose in 0.2% Sodium Chloride Solution) until diuresis is established should precede potassium administration. Although temporary elevation of the serum potassium level due to renal insufficiency secondary to dehydration or shock may mask an intracellular potassium deficit, do not replenish potassium until renal function has been reestablished by overcoming dehydration and shock.

Interactions

An increase in the extracellular potassium concentration reduces the effect of cardiac glycosides, a reduction increases the arrythmogenic effect of cardiac glycosides.

Potassium-saving diuretics, aldosterone antagonists, potassium-containing electrolyte substitutes, ACE inhibitors, nonsteroid anti-inflammatories and peripheral analgesics reduce the renal excretion of potassium. Severe hyperkalaemia can occur on simultaneous administration with potassium chloride.

Severe hyperkalaemia, with adverse effect on the heart rhythm, can also occur when suxamethonium and potassium are administered simultaneously.

Special warnings

Concentrated Sterile Solution containing 14.9% Potassium Chloride should only be administered with caution when there is

- cardiac decompensation
- simultaneous treatment with potassium-saving diuretics, aldosterone antagonists, ACE inhibitors or potentially nephrotoxic medicaments (nonsteroid anti-inflammatories etc.).
- prolonged or severe diarrhea, familial periodic paralysis, hypoadrenalism, hyponatremia and myotonia congenita.

The administration of potassium-containing infusions must be discontinued if there are signs of renal insufficiency.

There are typical changes in the ECG when the potassium balance is disturbed (hypo- or hyperkalaemia). However, there is no linear relationship between the ECG changes and the concentration of potassium in the blood.

When serum sodium or calcium concentration or pH is reduced, moderate elevation of serum potassium may cause toxic effects on the heart and skeletal muscle. Weakness and later paralysis of voluntary muscles, with consequent respiratory distress and dysphagia, are generally late signs, sometimes significantly preceding dangerous or fatal cardiac toxicity.

Usage in metabolic acidosis

Treat associated hypokalaemia with an alkalinizing potassium salt (e.g. potassium bicarbonate, potassium citrate or potassium acetate).

Pregnancy: Category C.

It is not known whether potassium salts can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Should be administered to a pregnant woman only if clearly needed.

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Date Signature

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Lactation
Exercise caution when administering to a nursing woman.

Dosage
Individualize dosage. Guide dosage and rate of infusion by ECG and serum electrolyte determinations.
The potassium deficit is calculated according to the following formula:
mmol potassium = kg body weight x 0.2 x 2 x [4.5 - current serum potassium (mmol/l)]. (Body weight x 0.2 represents the extracellular fluid volume.)

Maximum daily dose
Not more than 2–3 mmol/kg body weight/day.

Maximum infusion rate
Up to 20 mmol potassium per hour in adults (corresponding to 0.3 mmol potassium/kg body weight/hour).

Children
IV infusion up to 3 mEq/kg/day. Adjust volume of administered fluids to body size.

Method of administration
Intravenously use. Use only diluted as an additive to infusion solutions. The potassium concentration in the infusion solution must not exceed 40 mmol/l. Suitable vehicle solutions are e.g. 5% or 10% glucose solutions, isotonic sodium chloride solution, Compound Sodium Lactate solution, or complete electrolyte solutions.
Do not infuse rapidly. Adjust rate of administration according to tolerance. Use of the largest peripheral vein and a small bore needle is recommended.
In addition to ECG effects, vein irritation may result when a potassium concentration greater than 40 mEq/l is infused.
Concentrated potassium solutions are for IV admixtures only; do not use undiluted. Direct injection may be instantaneously fatal.
In critical states, potassium chloride may be administered in saline (unless saline is contraindicated) since dextrose may lower serum potassium levels by producing an intracellular shift.
Concentrated Sterile Solution containing 14.9% Potassium Chloride should only be added immediately before setting up the infusion and strictly aseptic technique should be observed. The infusion bottle should then be gently shaken.
As a matter of principle, infusion pumps should be used for the infusion of potassium in the setting of correction therapy.

Overdose
Symptoms
Overdose may cause hyperkalaemia, in particular in the presence of acidosis or kidney insufficiency.
The symptoms of hyperkalaemia are primarily cardiovascular disorders. There can be bradycardia, AV blockade and ventricular fibrillation and cardiac arrest. In the ECG there are high, sharp, symmetrical T-waves and, at very high potassium levels, broadening of the QRS complex. The vascular effects are hypotension and centralisation.
The neuromuscular symptoms encompass fatigue, weakness, states of confusion, heaviness of limbs, muscle twitching, paraesthesia, and ascending paralysis.
Plasma potassium concentrations greater than 6.5 mmol/l are dangerous, over 8 mmol/l often lethal.
It is important to consider the entire clinical condition and not to rely solely on potassium levels since only extracellular potassium can be measured, while intracellular potassium accounts for 98% of the total body amount.

Emergency treatment, antidotes
The first measure is immediate stop of infusion. Further corrective measures include slow intravenous administration of 10% calcium gluconate, infusion of glucose together with insulin, increase of diuresis, oral or rectal administration of cation exchangers, correction of acidosis, if necessary.
In cases of severe intoxication haemodialysis may be necessary.

Undesirable effects
Administration of potassium chloride may be accompanied by nausea, vomiting, abdominal pain, diarrhea, acidosis and elevated concentration of chloride in the blood.
Too rapid infusion may lead to heart arrhythmia. Hyperkalaemia may occur.
Local tissue necrosis and subsequent sloughing may result if extravasation occurs. Chemical phlebitis and venospasm have also been reported. Potassium solutions of 30 to 40 mEq/l concentration may cause pain at the injection site or phlebitis.
Should perivascular infiltration occur, discontinue IV administration at that site. 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.
Note: Patients are advised to inform their doctor or pharmacist of any adverse effect they experience in connection with the administration of this drug.

Expiry date
Do not use after the expiry date stated on the labelling.
Shelf life - 36 months.

Storage
Do not store above 25 °C.

Instructions for storage/use/handling
Only to be used if solution is clear and container undamaged.
The product is supplied in single-dose containers. Unused portions must be discarded.

License number
117-63-29912

Manufacturer
B. Braun Melsungen AG
34209 Melsungen

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