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Directions for use
Read carefully!

Potassium Chloride

14.9% Solution for IV infusion
Parenteral Electrolyte

Formulation
100 mL solution contains:
Potassium Chloride 14.9 g

Excipient
Water for Injections

1 mL contains 2 mmol potassium and 2 mmol chloride.

Pharmaceutical form
Concentrate for solution for infusion

Pharmaco-therapeutic group
Electrolyte replacement solutions

Indications
States of potassium deficiency, especially if accompanied by alkali excess and decreased chloride concentration in the blood (hypochloraemic alkalosis).

Contraindications
Potassium Chloride Concentrate 14.9% 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.

Special warnings and precautions for use
Potassium Chloride Concentrate 14.9% 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.).

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.

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

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

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, 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.

Dosage
The dosage should be adjusted according to the analysis values of the serum ionogram and the acid base status.

The potassium deficit is calculated according to the following formula:

mmol potassium =
kg BW 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 BW/day

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

Method of administration
Intravenously, 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.

Potassium Chloride Concentrate 14.9% 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.

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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.

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, acidosis, an elevated concentrations of chloride in the blood.

Too rapid infusion may lead to heart arrhythmia.

Note:

Patients are advised to inform their doctor or pharmacist if they notice any adverse effect not mentioned in this leaflet.

Caution

Foods, Drugs, Devices & Cosmetics Act prohibits dispensing without prescription.

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph.

Seek medical attention immediately at the first sign of any adverse drug reaction.

Usage during pregnancy

No adverse reaction has been reported. However, these injections should be given to a pregnant woman only if clearly needed.

Storage

Store below 30°C.

Shelf life

The product must not be used beyond the expiry date stated on the label.

Availability

Plastic Polyampoule x 10mL (Box of 20's);
Plastic Polyampoule x 20mL (Box of 20's)

Instructions for use/handling

Only to be used if solution is clear and container undamaged.

The product is supplied in single-use containers.
Unused portions must be discarded.

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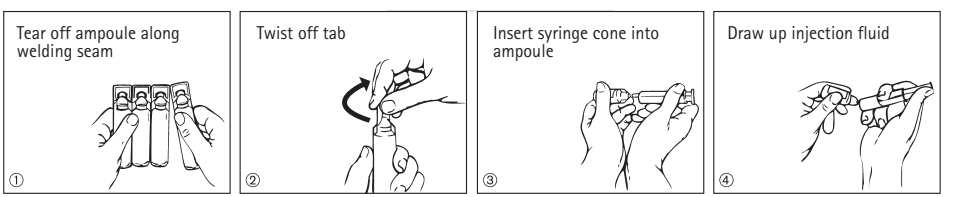

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