POTASSIUM CHLORIDE 14.9 %

Scheduling status:

S1

Composition:

10 ml of solution contains 1,49 g Potassium Chloride.

Theoretical osmolarity: 3995 mOsm/l

pH: 4,5 - 7,5

Pharmacological classification:

A. 24 Mineral substitutes, electrolytes

Pharmacological action:

Potassium has an important role in:

- electrical excitability of the cells
- acid-base disturbances and potassium depletion (homeostasis)
- cellular metabolism

Pharmacokinetics:

Potassium is excreted mainly by the kidneys; it is secreted in the distal tubules in exchange for sodium or hydrogen ions. The capacity of the kidneys to conserve potassium is poor and some urinary excretion of potassium continues when there is severe depletion. Some potassium is excreted in the faeces and small amounts may also be excreted in sweat.

Indications:

Hypokalaemia.

Contra-indications:

Potassium Chloride B. Braun 14,9% must not be administered when there is:

- Hyperkalaemia

- Hyperchloraemia

- Disorders that are frequently associated with hyperkalaemia such as dehydration, reduced renal excretion, early post-operative oliguria, adrenocortical insufficiency, periodic paralysis, sickle cell anaemia.

Warnings:

Potassium Chloride B. Braun 14,9% must be diluted with not less than 50 times its volume of 0,9% Sodium Chloride injection or other suitable diluent before use.

Interactions:

Potassium sparing diuretics, aldosterone antagonists inhibitors, angiotensinconverting enzyme (ACE) inhibitors and non-steroidal anti-inflammatory agents 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.

Pregnancy and lactation:

Safety during pregnancy and lactation has not been established.

Dosage and directions for use:

Adults

Do not administer undiluted. Dilute in a large volume of parenteral solution. Two 10 ml vials/ampoules or one 20 ml vial/ampoule in 1000 ml produces a 40 mmol potassium concentration per litre. The potassium should not exceed 40 mmol/litre. To prevent potassium “layering”, the container should be agitated thoroughly. Preferably an infusion of potassium-free solution (1000 ml) should be given prior to infusion with Potassium Chloride B. Braun 14,9% to

demonstrate adequate renal function. The diluted potassium solution should be given under ECG control with an infusion rate not exceeding 30 mmol per hour. Potassium Chloride B. Braun 14,9% should only be added immediately before setting up the infusion and strict aseptic technique should be observed.

Side effects and special precautions:

Side Effects:

Blood disorders:

The following side effects have been reported but the frequency is unknown:

Hyperkalaemia (symptoms include paraesthesia of the extremities, mental confusion, weakness, paralysis, cardiac arrhythmias); acidosis; an elevated concentration of chloride in the blood.

General disorders and administration site conditions:

The following side effects have been reported but the frequency is unknown:

Pain or phlebitis at the injection site.

Gastrointestinal disorders:

The following side effect has been reported but the frequency is unknown:

Nausea.

Cardiac disorders:

The following side effects have been reported but the frequency is unknown:

Too rapid infusion may lead to cardiac arrest.

Special precautions:

Potassium Chloride B. Braun 14,9% injection should be administered with caution when there is:

- Simultaneous treatment with potassium sparring diuretics, aldosterone antagonists, ACE inhibitors or potentially nephrotoxic medicaments (see Interactions).

The administration of Potassium Chloride B. Braun 14,9% 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.

Known symptoms of overdosage and particulars of its treatment:

Overdose may cause hyperkalaemia, in particular in the presence of acidosis or kidney insufficiency. Hyperkalaemia may cause toxic effects on the heart and skeletal muscles. Weakness and later paralysis of voluntary muscles with consequent respiratory distress and dysphagia are generally later signs. In the acute management of hyperkalaemia, the discontinuation of Potassium Chloride B. Braun 14,9% administration is essential. Further treatment is symptomatic and supportive.

Identification:

Clear, colourless solution, practically free from particles.

Presentation:

Carton containing 20 x 10 ml or 20 x 20 ml polyethylene ampoules.

Storage instructions:

Store at or below 25 °C.

Single dose container. Discard any unused portion.

Keep out of reach of children.

Registration number:

A39/24/0621

Name and business address of the holder of the certificate of registration:

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