Galenica Senese Potassium chloride 2 mEq/ml concentrate for solution for infusion
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PHARMACO-THERAPEUTIC GROUP

Electrolytic solutions.

THERAPEUTIC INDICATIONS

Treatment of potassium deficiencies in patients for whom oral reintegration is not possible.

CONTRAINDICATIONS

- Hypersensitivity to the active substance or to any of the excipients;
- hyperkalaemia or in cases of potassium retention;
- severe renal insufficiency;
- untreated Addison's disease;
- acute dehydration;
- heat cramps.

PRECAUTIONS FOR USE

High blood concentrations of potassium can cause death from heart failure, arrhythmias or arrest. To avoid potassium poisoning, the infusion must be slow.

Administration should be guided through serial electrocardiograms; serum potassium levels are not indicative of potassium cell concentrations. It is good practice to monitor the fluid, electrolytes and acid-base balance during the infusion.

The medicinal product should be administered with caution in patients:

- with renal insufficiency (administration of solutions containing potassium ions in patients with decreased renal function may cause potassium retention);
- with heart failure, particularly if digitalised;
- with adrenal insufficiency;
- with hepatic failure;
- with hypokalemic periodic paralysis;
- with congenital myotonia;
- in the early post-operative phases.

INTERACTIONS

Tell your doctor or pharmacist if you have recently taken any other medicinal product, including medicines obtained without a prescription.

The use of drugs such as potassium-sparing diuretics may increase the risk of hyperkalaemia, particularly in the presence of renal dysfunction. Therefore, in such cases serum potassium levels must be monitored closely.

The use of medicinal products such as ACE inhibitors that cause a decrease in aldosterone levels can lead to potassium retention. Therefore, serum potassium levels must be monitored closely.

SPECIAL WARNINGS

The solution must be clear, colourless and free from visible particles. Use immediately after opening the container. The container must be used for a single uninterrupted administration and no residue may be used afterwards.

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice before taking any medicine.

There are no data on possible adverse effects of the medicinal product when administered during pregnancy or breastfeeding or concerning the reproductive capacity.

Therefore, the medicinal product must not be used during pregnancy and breastfeeding unless clearly necessary and only after assessing the risk/benefit ratio.

Effects on ability to drive and use machines

The medicine does not affect the ability to drive or use machines.

POSOLOGY AND METHOD OF ADMINISTRATION

The medicine must not be injected as such. It is fatal if infused undiluted (see Precautions for use).

The medicinal product should be administered intravenously only after dilution in a 5% glucose or 0.9% sodium chloride solution (saline solution) or other compatible solutions (see end of this section).

Shake well when preparing the dilution and before administration.

The dose depends on the patient's age, weight and clinical condition, taking into account that the ordinary daily potassium requirement is as follows

Adults: 40-80 mEq per day. The total dose must not exceed 200 mEq per day.

Children: 2-3 mEq/kg per day.

The safety and efficacy parameters of potassium chloride have not been determined in children.

The medicinal product must only be administered with an intact renal function and at a rate not exceeding 10 mEq potassium/hour.

Under urgent conditions (potassium values less than or equal to 2 mEq/l with electrocardiographic changes and muscular paralysis) do not exceed the infusion rate of 40 mEq/h, under electrocardiographic monitoring and do not exceed the dose of 400 mEq in 24 hours.

Too fast infusions can cause local pain and the infusion rate should be adjusted in relation to tolerance.

Incompatibility with Galenica Senese Potassium chloride

Unless otherwise indicated, and with the exception of the solutions indicated below, it is not recommended to mix the potassium chloride solution with other medicinal products.

Solutions to be used for the dilution of Galenica Senese potassium chloride

See Posology and method of administration.

Dilute the solution immediately after opening the container; the diluted solution must be used immediately. This must be clear, colourless and free from visible particles. The container must be used for a single uninterrupted administration and no residue may be used afterwards.

Shake well when preparing the dilution and before administration. Do not use the medicine if the solution is not clear, colourless or should it contain particles.

Take all usual precautions to maintain everything sterile before and during the intravenous infusion.

OVERDOSE

In case of overdose, immediately stop the infusion of the potassium-containing solution and establish a corrective therapy to reduce the high plasma levels of potassium and to restore, if necessary, the acid-base balance (see Precautions for use).

In case of accidental ingestion/intake of an excessive dose of Galenica Senese Potassium Chloride, inform your doctor immediately or contact your nearest hospital.

Should you have any further questions or doubts on the use of Galenica Senese Potassium Chloride, contact your doctor or pharmacist.

ADVERSE EFFECTS

Like all medicinal products, Potassium Chloride can cause adverse effects, although not everybody has these.

The adverse effects of Potassium Chloride are listed below. There is insufficient data available to establish the frequency of the single effects listed.

Gastrointestinal diseases

Gastrointestinal disorders.

Nervous system diseases

Neuromuscular disorders, paraesthesia, flaccid paralysis, weakness, mental confusion.

Cardiac disorders

Hypotension, arrhythmias, conduction disturbances, P wave disappearance, QRS widening in the ECG trace, cardiac arrest.

Disorders of the water and electrolyte balance

Hypervolemia.

General disorders and administration site conditions

Febrile responses, infections at the injection site, venous thrombosis or phlebitis, extravasation.

Compliance with the instructions contained in the package leaflet reduces the risk of adverse effects.

Should any of the adverse effects worsen, or if you notice any adverse effect not listed in this leaflet, please tell your doctor or pharmacist.

EXPIRY DATE AND STORAGE

Expiry date: see the expiry date on the package.

The expiry date refers to the product in its intact packaging, correctly stored.

Warning: do not use after the expiry date shown on the package.

Storage conditions

Store in the original package and in the tightly closed container. Do not refrigerate or freeze.

Medicinal products should not be disposed of via wastewater or household waste. Ask the pharmacist how to dispose of the medicines you no longer use. This will help to protect the environment.

Keep the medicinal product out of the reach and sight of children.

COMPOSITION

Galenica Senese Potassium chloride 2 mEq/ml concentrate for solution for infusion

10 ml of solution contains:

Active substance: potassium chloride 1.49 g (each ml contains 2 mEq of K^+ of Cl^-)

Excipients: Water for injections q.s. to 10 ml.

pH: 5.5 - 6.5

Galenica Senese Potassium chloride 3 mEq/ml concentrate for solution for infusion

10 ml of solution contains:

Active substance: potassium chloride 2.24 g (each ml contains 3 mEq of K^+ of Cl^-)

Excipients: Water for injections q.s. to 10 ml.

pH: 5.5 - 6.5

PHARMACEUTICAL FORM AND CONTENT

Sterile and pyrogen-free concentrate for solution for infusion.

Package size:

1 10 ml glass ampoule

5 10 ml glass ampoules

10 10 ml glass ampoules

MARKETING AUTHORISATION HOLDER

Industria Farmaceutica Galenica Senese S.r.l.

MANUFACTURER

Industria Farmaceutica Galenica Senese S.r.l.

Review of the package leaflet by the Italian Medicines Agency:

20 February 2013

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