Package leaflet: Information for the user

Potassium Chloride 15% w/v concentrate for solution for infusion

Potassium chloride

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Potassium Chloride is and what it is used for

This product belongs to the group "Additives for intravenous solutions': Electrolytic solutions" and it is dispensed under medical prescription.

Potassium Chloride is indicated for the treatment of potassium deficiency in patients for whom dietary measures or oral medication are inadequate.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you use Potassium Chloride

Do not use Potassium Chloride:
You must not be given Potassium Chloride if you suffer from excess of potassium in the blood (hyperkalaemia).

Warnings and precautions
Talk to your doctor before using Potassium Chloride.
Potassium Chloride will be given by or under the direct supervision of your physician, who will take care for the following:
- Direct injection of potassium chloride concentrates without appropriate dilution may cause instant death.
- The administration should be slow (usually 10 mmol/h, not exceeding 20 mmol/h) and under control of cardiac activity.
- Since adequate urine flow must be ensured, your urine flow should be monitored.
- Your serum electrolyte levels and acid-base status should be monitored and the dose should be adjusted to your individual needs.

- Closely monitor patients with diseases of the heart, acute fluid deficiency (acute dehydration), heat cramps, extensive tissue destruction as occurs with severe burns, and elderly patients since renal function may be impaired or other conditions predisposing to excess of potassium in the blood (hyperkalaemia) may be present.
- Initial potassium replacement therapy should not involve glucose infusions, because glucose may cause a further decrease in the plasma-potassium concentration.
- If signs of renal failure occur, intravenous administration of potassium-containing solutions should be stopped.

Your doctor may need to take special precautions and will decide whether you can receive Potassium Chloride if you suffer from:
- uncompensated heart failure (decompensated cardiac insufficiency), if you are under treatment with digitalis (medicines used for the treatment of diseases of the heart), and if you have severe or complete heart block.
- conditions which are frequently associated with an excess of potassium in the blood (hyperkalaemia): Gamstorp episodic adynamy (a form of periodic paralysis), sickle cell anaemia, impaired function of the adrenal glands (adrenal insufficiency), decreased renal function (renal insufficiency), low urinary output after surgery (post-operative oliguria), shock with disintegration of red blood cells and/or deficiency of body fluid (shock with haemolytic reactions and/or dehydration), metabolic acidosis (form of acidic blood), treatment with potassium-sparing diuretics (medicines used to increase urine excretion that retain potassium in the blood), excess of chloride in the blood (hyperchloraemia).

Your doctor should pay attention on intravenous administration since leakage of infusion fluid out of the vessel (extravasation) can cause tissue death (necrotic tissue damages).

Children
The safety and efficacy of potassium chloride for paediatric patients has not been fully established.

Other medicines and Potassium Chloride

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

Combinations not recommended (except in cases of severe potassium deficiency):
+ Potassium-sparing diuretics (medicines used to increase urine excretion that retain potassium in the blood), single or combined such as: amiloride, spironolactone, triamteren, potassium canrenoate, eplerenone; risk of potentially fatal excess of potassium in the blood (hyperkalaemia), particularly in patients with renal impairment (addition of potassium increasing effects).
+ Angiotensin converting enzyme inhibitors (ACE), angiotensin II receptor antagonists, non-steroidal anti-inflammatory drugs (NSAIDs), cyclosporin, tacrolimus, suxamethonium: potentially fatal excess of potassium in the blood (hyperkalaemia), particularly in patients with renal impairment (addition of potassium increasing effects).
+ Blood products, penicillin potassium salts: potential risk of potassium excess in the blood (hyperkalaemia) due to the amount of potassium present in these products.

Combinations possible with special precautions of use:
+ Quinidine: potassium can increase the anti-arrhythmic effects of quinidine.
+ Thiazides, adrenocorticoids, glucocorticoids, mineralocorticoids: Effects of the potassium supplement may be decreased.
+ Digoxin: excess of potassium in the blood (hyperkalaemia) can be dangerous if you take digitalis medicines for the treatment of diseases of the heart,
+ Exchange resins: the serum levels of potassium are reduced by replacing potassium with sodium.

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

However physical incompatibility of Potassium Chloride 15 % w/v concentrate for solution for infusion has been reported with the following medicinal substances: amikacin, amphotericin B, dobutamine, fat emulsions, mannitol solutions 20% - 25% and sodium G penicillin.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking any medicine.

There are no or limited amount of data from the use of potassium chloride in pregnant women.
The use of Potassium Chloride 15 % w/v concentrate for solution for infusion may be considered during pregnancy if clinically needed.

Potassium Chloride is excreted in human milk to such an extent that effects on the breastfed newborn/infants are likely.
A risk to the newborns/infants cannot be excluded.
Your doctor must decide whether to discontinue breast-feeding or to discontinue/abstain from Potassium Chloride 15 % w/v concentrate for solution for infusion taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

Driving and using machines
There is no evidence that this product could affect the ability to drive vehicles or manipulate complex machinery.

3. How to use Potassium Chloride

Potassium Chloride will be given by, or under direct supervision of your physician, who will closely control the amount of Potassium Chloride given to you.

Your doctor will decide on the correct dose for you to receive.

The recommended dose for adults and adolescents is:
Administer intravenously only after dilution in a suitable solution, up to a maximum concentration of 3 g/l of potassium chloride (or 40 mmol/l of potassium). For therapy of severe hypokalaemia or diabetic ketoacidosis higher concentrations may be necessary. In this case, the infusion should be into a high blood flow vein and continuous ECG monitoring is advisable.

1 g of potassium chloride corresponds to 13.4 mmol or 524 mg of potassium.

Dose is dependent on results of serum electrolyte levels and acid-base-state. The potassium deficit is to be calculated via the following formula:
Potassium deficit (mmol) = kg body weight x 0.2 x 2 x (4.5 mmol/l – serum potassium)
(The extracellular volume calculates from body weight in kg x 0.2.)

Normal daily intake is approximately 0.8 to 2 mmol of potassium per kilogram of body weight.

Usually, the maximum dose for adults should not exceed 150 mmol per day.

Use in children:
Intravenous administration after dilution in a suitable solution up to a maximum dose of 3 mmol of potassium/kg of body weight, or 40 mmol/m^2 of body surface is recommended. For children weighing 25 kg or over, refer to the adult dosage.

Maximum dose for children is 3 mmol/kg of body weight and day.

In patients with renal impairment dose should be reduced.

Route of administration:
You will receive this medicine diluted by infusion into a vein (intravenous drip). The infusion rate will be slow, the amount of potassium chloride will depend on your specific requirement.

A rate of 10 mmol/h is normally considered safe. As a general rule the rate should never be higher than 20 mmol/h.

The administration via an infusion pump is recommended, especially for solutions with higher concentrations.

Your doctor will tell you how long the treatment with Potassium Chloride should last.

If you think that the action of Potassium Chloride is too strong or weak tell your doctor or pharmacist.

If you use more Potassium Chloride than you should

Overdose as a result of potassium excess in the blood can produce ECG abnormalities, lowered heart rate (bradycardia), irregular heart rhythm with very rapid, uncoordinated, fluttering contractions of the lower chambers of the heart (ventricular fibrillation), other rhythm disorders of the heart (arrhythmias) up to cardiac arrest, confusion, tiredness, diarrhoea, swallowing disorders, abnormal skin sensations felt in the arms or legs (paraesthesia of the extremities), breathing difficulty, skeletal muscles paralysis, and death.

If any of these effects appear, immediately stop the treatment and avoid any potassium containing food and potassium-sparing diuretics (medicines used to increase urine excretion that retain potassium in the blood).

In case of overdose or accidental use, contact an emergency centre immediately indicating the medicine and quantity used.

If you experience any of these symptoms or think you may have received too much Potassium Chloride, tell your doctor or healthcare personnel immediately.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Excessive intake of potassium may cause potassium excess in the blood (hyperkalaemia) which may cause neuromuscular and heart disorders, especially rhythm disorders, and even cardiac arrest can occur.

Further undesirable effects:

Metabolism and nutrition disorders:
- acidic blood (acidosis),
- excess of chloride in the blood (hyperchloraemia).

Vascular disorders:
- blood clot inside a blood vessel (venous thrombosis).

General disorders and administration site conditions:
- nausea
- pain at the injection site,
- cellular death in case of leakage of infusion fluid out of the vessel (extravasation),
- venous inflammation in case of too high local concentrations.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

For UK
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

For Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

5. How to store Potassium Chloride

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the ampoule and outer carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not use this medicine if the solution is cloudy, contains any visible particle, or shows discolouration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Potassium Chloride contains

The active substance is potassium chloride.

The only excipient is water for injections.

Each 1 ml of solution contains 150 mg of potassium chloride (15 % w/v) equivalent to 2 mmol potassium ions.

Each 5 ml of solution contain 750 mg of potassium chloride (15 % w/v) equivalent to 10 mmol potassium ions.

Each 10 ml of solution contain 1500 mg of potassium chloride (15 % w/v) equivalent to 20 mmol potassium ions.

Each 20 ml of solution contain 3000 mg of potassium chloride (15 % w/v) equivalent to 40 mmol potassium ions.

Ionic content: K^+ 2000 mmol/l

Cl^- 2000 mmol/l

Theoretical osmolarity: 4000 mosm/l

What Potassium Chloride 15 % w/v concentrate for solution for infusion looks like and contents of the pack

Potassium Chloride 15 % w/v concentrate for solution for infusion is a clear, colourless solution.

Potassium Chloride 15 % w/v concentrate for solution for infusion is presented in the following formats:
Package with 20 ampoules containing 5 ml
Package with 50 ampoules containing 5 ml
Package with 20 ampoules containing 10 ml
Package with 50 ampoules containing 10 ml
Package with 20 ampoules containing 20 ml

Not all pack sizes may be marketed.

Instructions for the correct administration:

Potassium Chloride 15% w/v is a sterile solution containing potassium chloride for i.v. infusion. It must be diluted by not less than 50-times its volume with isotonic Sodium Chloride (0.9%, w/v) solution for infusion or another suitable solution for infusion.

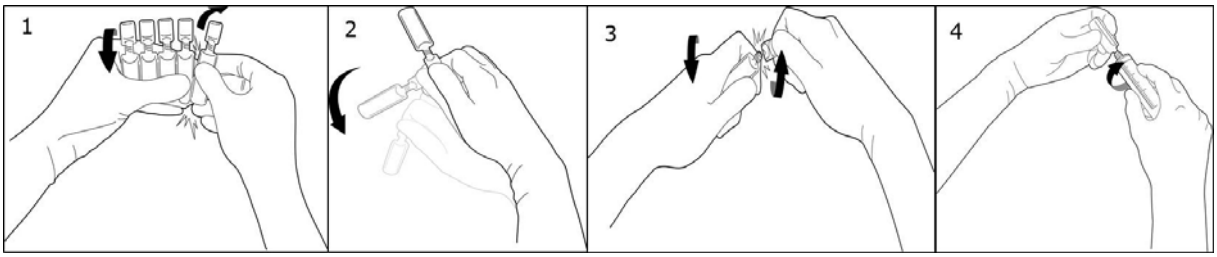
Compatibility of Potassium Chloride with any other infusion solution should be established prior to dilution.

In order to avoid a bad homogenization of the diluted solution, the concentrated solution of Potassium Chloride should not be added to a bottle/bag of infusion in hanging position. Once the concentrated solution has been added to the bottle/bag of infusion, the product must be mixed well before use, so shake the bottle/bag carefully with 3-5 slow movements in order to get a good product homogenization. Then, hang the bottle/bag and start the infusion process.

For single use only. Always use diluted!

Handling instructions

To break off a single ampoule, twist one ampoule against the remaining ampoules of the pack without touching the head and neck of the ampoules (1). Shake the ampoule with one single movement as shown below in order to remove the liquid kept in the cap (2). To open the ampoule, twist the ampoule body and the ampoule head in opposite directions until the neck breaks off (3). Connect the ampoule to the luer-syringe or luer-lock syringe as shown in figure (4).



Therefore, no needle is needed to extract the solution. Extract the liquid.

Marketing Authorisation Holder and Manufacturer:
Marketing Authorisation Holder:

For UK
Fresenius Kabi Ltd
Cestrian Court
Eastgate Way, Manor Park
Runcorn, Cheshire, WA7 1NT
United Kingdom

For IE
Fresenius Kabi Deutschland GmbH
Else-Kröner-Straße 1,
61352 Bad Homburg v.d.Höhe
Germany

Manufacturer:
FRESENIUS KABI ESPAÑA, S.A.
C/ Marina 16 – 18,
08005 Barcelona, Spain

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium	Kaliumchloride Fresenius Kabi 150 mg/ml concentraat voor oplossing voor infusie
Estonia	Potassium Chloride Kabi 150 mg/ml, infusioonilahuse kontsentraat
Germany	Kaliumchlorid Kabi 150 mg/ml Konzentrat zur Herstellung einer Infusionslösung
Greece	POTASSIUM CHLORIDE/FRESENIUS 150 MG/ML
Ireland	Potassium Chloride 15% w/v concentrate for solution for infusion

Lithuania	Potassium chloride Kabi 150 mg/ml koncentratas infuziniam tirpalui
Latvia	Potassium chloride Kabi 150 mg/ml koncentrāts infūziju šķīduma pagatavošanai
Poland	Potassium chloride 150 mg/ml - Concentrate for solution for injection or infusion
Portugal	Cloreto de potássio Kabi
Romania	Clorura de potasiu Kabi 150 mg/ml
Spain	Cloruro de potasio Meinsol 2 mEq/ml solución inyectable
United Kingdom	Potassium Chloride 15% w/v concentrate for solution for infusion

This leaflet was last revised in 10/2021