Package leaflet: Information for the user

Potassium Chloride 0.3% w/v and Sodium Chloride 0.9% w/v Solution for Infusion

Potassium chloride and sodium 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 0.3% w/v and Sodium Chloride 0.9% w/v is and what it is used for

This medicine contains a solution of potassium chloride and sodium chloride. It is administered given to you through a tube placed into a vein (intravenous drip).
You will receive it to maintain or restore your potassium, sodium, chloride and fluid levels when the levels are low.

2. What you need to know before you use this medicine

Do not use Potassium Chloride 0.3% w/v and Sodium Chloride 0.9% w/v

- if you have high levels of potassium (hyperkalaemia) or chloride (hyperchloraemia) or too high levels of sodium (severe hypernatraemia) in your blood
- if you have serious kidney disease
- if you have too much water in your body (hyperhydration)

Warnings and precautions

Talk to your doctor before you are given Potassium Chloride 0.3% w/v and Sodium Chloride 0.9% w/v

Before or when giving you this medicine, your doctor will pay special attention to the following:

- High levels of sodium in your blood (hypernatraemia)

- Swelling of the lower limbs (oedematous states) or water on your lungs (pulmonary oedema):
  If you have one of these conditions, you will be given large amounts of this medicine only carefully.

- Kidney and liver function:
  You will receive this medicine as a slow intravenous drip after your doctor has made sure that your kidneys and liver are working properly. If they don't do so, your potassium blood levels and your heart will be monitored while you receive this medicine. Your doctor will make sure to stop the infusion in case your condition worsens.

- Heart disease:
  If you suffer from a heart disease, this medicine will be given to you with caution.

If you have high levels of acidic substances in your blood your doctor will take special care when giving you this solution.

Your doctor will take special care if you have Addison's disease (a specific disease of the adrenal gland) as your potassium levels might become too high.

The rhythm of your heart your fluid balance, the salts in your blood and your level of sodium chloride will be monitored while you are receiving this medicine.

If you are elderly, you are more likely to suffer from heart and kidney problems, will be closely monitored during treatment and the dosage will be carefully adjusted.

Children
This medicine will be given to your child only with special caution. Their doctor will closely monitor their salt and fluid balance.

Other medicines and Potassium Chloride 0.3% w/v and Sodium Chloride 0.9% w/v
Tell your doctor if you are taking, have recently taken or might take any other medicines.

If you are taking digoxin or similar medicines that help your heart to work better, tell your doctor as it may change how they work. The amount of Potassium Chloride 0.3% w/v and Sodium Chloride 0.9 % w/v may have to be adjusted, especially at the end of therapy.

Also tell your doctor if you are taking medicines that contain potassium or may lead to high potassium levels, such as
• potassium-sparing medicines e.g. spironolactone or triamterene (medicines that increase urine flow)
- ACE inhibitors (medicines to treat high blood pressure or heat failure)
- Angiotensin II receptor antagonists (a type of blood pressure medicine)
- non-steroidal anti-inflammatory agents (for sudden or long lasting pain and inflammation)
- ciclosporin, tacrolimus (medicines that are used after an organ transplant)
- suxamethonium (a medicine that is used during operations to put you to sleep).

They will take special care of you if you receive/take medicines that make you hold on to potassium as these may lead to heart problems (cardiac arrhythmia).
Also, you doctor will take care if you use medicines that make you hold on to sodium because these may lead to swelling due to a build up of water (oedema).

If you are taking certain medicines, namely corticosteroids, (used to treat a wide range of diseases such as asthma, hayfever, hives, eczema, painful joints or muscles, pain caused by a trapped nerve, inflammatory bowel disease, lupus, multiple sclerosis), ACTH (used to treat a wide variety of diseases such as spasms in infants and children, multiple sclerosis, arthritis, lupus, Stevens-Johnson syndrome) and loop diuretics (for high blood pressure), the amount of potassium lost through your kidneys can be increased.

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

This medicine can be given while you are pregnant or breast-feeding if your doctor thinks it is necessary.

Driving and using machines

Potassium Chloride 0.3% w/v and Sodium Chloride 0.9 % w/v has no influence on the ability to drive or use machines.

3. How to use Potassium Chloride 0.3% w/v and Sodium Chloride 0.9% w/v

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Dose
The recommended dose that you will be given will be determined by your doctor. It will depend on your age, weight and condition, especially if your heart or kidneys do not work properly. While you receive this medicine your blood sodium chloride and electrolyte (salt) levels, water balance and heart will be checked regularly. Your doctor will make sure that your urine flow is sufficient.

The recommended maximum dose for an adult is 40 ml/kg body weight/day.

In cases where more potassium is needed, your doctor will think about using other strengths as well.

This medicine may be given to you as long as you need salts and fluid via a drip into your vein.

Elderly

In principle, the same dose as for adults can be used. However, if you are elderly it might be necessary to adjust the dose stated to avoid heart or kidney problems.

Use in children and adolescents
In children and adolescents the dose will depend upon the individual needs. Therefore, your child may receive a reduced dose.

Method of administration
The medicine will be administered to you through a tube placed into a vein (intravenous drip).

If you receive more Potassium Chloride 0.3% w/v and Sodium Chloride 0.9% w/v than you should
It is unlikely that this occurs because your doctor will determine your daily doses.

Signs of an overdose

If you have received too much of this medicine or you have kidney problems your salt levels and water and acid-base balance may be affected. You may also experience tissue fluid accumulation and potassium intoxication. If your sodium level increases too rapidly your brain may become damaged (osmotic demyelination syndrome). Potassium blood levels may especially be excessively increased. Signs of such disorder may be:

- Low blood pressure (hypotension)
- Irregular heart beats or your heart stops beating
- General weakness and listlessness
- Muscle weakness, inability to move
- Very marked numbness, weakness or heaviness of your legs
- Confusion.

If you have received too much chloride this may cause a loss of bicarbonate and consequently high levels of acidic substances in your blood.

Actions to be taken in case of an overdose
In such a case the infusion rate will be stopped immediately You may also be given medicines that increase your urine flow. Your heart rate will be monitored continuously. Your doctor will decide on further medication such as insulin or other measures to bring your salt levels, water balance and acid-base balance back to normal.

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 cause side effects, although not everybody gets them. When this medicine is used according to the directions, it is very unlikely that side effects occur. Tell your doctor if you notice pain or tenderness or inflammation or blood clots at the site of injection.

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.

United Kingdom:
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

Ireland:
HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.
Website: www.hpra.ie; e-mail: medsafety@hpra.ie

5. How to store Potassium Chloride 0.3% w/v and Sodium Chloride 0.9% w/v

Keep this medicine out of the sight and reach of children.
Do not use Potassium Chloride 0.3% w/v and Sodium Chloride 0.9% w/v after the expiry date which is stated on the label of the bottles and the carton. The expiry date refers to the last day of that month.
This container is for single use only. After use discard container and any remaining contents.
Do not reconnect partially used containers.
Do not use the product if the solution appears cloudy or discoloured, if you find particles in the solution or if the bottle and its closure are damaged.

The equipment to be primed with the solution in order to prevent air entering the system.

In case of an adverse reaction, infusion must be stopped immediately.

The product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

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.

Do not store above 25°C.

6. Contents of the pack and other information

What Potassium Chloride 0.3% w/v and Sodium Chloride 0.9% w/v Solution for Infusion contains
• The active substances are potassium chloride and sodium chloride.

1 ml of solution for infusion contains:
Potassium chloride 3.0 mg
Sodium chloride 9.0 mg

1 litre of solution for infusion contains 40 mmol potassium, 154 mmol sodium and 194 mmol chloride.

• The other ingredient is water for injections.

- Theoretical osmolarity 380 mOsmol/l
  pH approximately 4.5- 7.0

What Potassium Chloride 0.3% w/v and Sodium Chloride 0.9% w/v Solution for Infusion looks like and contents of the pack
Solution for infusion
Potassium Chloride 0.3% w/v and Sodium Chloride 0.9% w/v Solution for Infusion is a clear, colourless solution of potassium chloride and sodium chloride in water.
It comes in plastic (polyethylene) bottles containing 500 ml or 1000 ml supplied in packs of 10 x 500 ml and 10 x 1000ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
B. Braun Melsungen AG
Carl-Braun-Strasse 1
34212 Melsungen, Germany

Postal address
34209 Melsungen

Phone: +49/5661/71-0
Fax: +49/5661/714567

Manufacturers
B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen, Germany

B. Braun Medical S.A.
Carretera de Terrassa 121
08191 Rubi, Barcelona, Spain

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The following information is intended for healthcare professionals only:

Posology

Adults:

The following recommendations are general guidelines on potassium, however prescribing should follow local guidelines.

Potassium

The amount required for correction of moderate potassium deficiency and in maintenance may be calculated according to the following formula:

mmol K+required = (body weight [kg] × 0.2)* × 2 × (serum-K+target** – serum-K+actual [mmol/l])

*Term represents the extracellular fluid volume
** should be 4.5 mmol/l

The maximum recommended dose of potassium is 2 – 3 mmol/kg body weight (b.w.)/24 h.

Paediatric population
Generally a substitution rate of 0.5 mmol/kg potassium BW per hour should not be exceeded. Continuous ECG monitoring should be applied during infusion.

Maximum daily dose

The maximum recommended dose of potassium is 3 mmol/kg BW per 24 hours. In any case the limits for daily fluid intake must not be exceeded.

Infusion rate

The infusion rate will depend on the conditions of the individual patient (see section 4.4).

In patients with chronic hyponatraemia the rate of infusion should be slow, so that the resulting increase of the serum sodium level is limited to a maximum of 0.35 mmol/l/h.

Method of administration
The maximum rate of Potassium 0.3% w/v and Sodium Chloride 0.9% w/v Solution for Infusion administration via peripheral lines is 10 mmol potassium per hour. For greater infusion rates, the solutions should be infused via a central line.
As a matter of principle, infusion pumps should be used for the infusion of potassium in the setting of correction therapy.

Contraindications

- Hyperkalaemia,
- Severe renal impairment with oliguria, anuria or azotaemia
- Hyperchloraemia and severe hypernatraemia,
- Hyperhydration.

Special warnings and precautions

Disorders where restriction of sodium intake is indicated, such as cardiac insufficiency, generalized oedema, pulmonary oedema, hypertension, pre-eclampsia, severe renal insufficiency.liver cirrhosis.
Sodium chloride supplementation must be exercised slowly in patients with chronic hyponatraemia as too rapid correction of serum sodium levels may in rare cases lead to osmotic side effects.

Paediatric population:

Premature or term infants may retain an excess of sodium due to immature renal function. In premature or term infants, repeated infusion of sodium chloride should therefore only be given after determination of the serum sodium level.

Incompatibilities

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

Shelf life after first opening the container

From a microbiological point of view, unless the method of opening precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.