

Package Leaflet: Information for the user

Potassium Chloride 2.98% 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.
- 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 2.98% w/v and Sodium Chloride 0.9% w/v is and what it is used for
2. What you need to know before you use Potassium Chloride 2.98% w/v and Sodium Chloride 0.9% w/v
3. How to use Potassium Chloride 2.98% w/v and Sodium Chloride 0.9% w/v
4. Possible side effects
5. How to store Potassium Chloride 2.98% w/v and Sodium Chloride 0.9% w/v
6. Contents of the pack and other information

1. What Potassium Chloride 2.98% 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 to you through a tube placed into a vein (intravenous drip).

This medicine is used in patients needing restoration of potassium level. Potassium helps your muscles, heart and other organs to work properly. Without the right amount of potassium your heart may start to beat abnormally, which could be life-threatening.

2. What you need to know before you use Potassium Chloride 2.98% w/v and Sodium Chloride 0.9% w/v

Do not use Potassium Chloride 2.98% w/v and Sodium Chloride 0.9% w/v:

- if you are allergic to potassium chloride or any of the other ingredients of this medicine
- if you have high levels of potassium (hyperkalaemia)
- if you have high levels of chloride in your blood (hyperchloremia)
- if you have too high levels of sodium in your blood (severe hypernatraemia)
- if you have severe kidney disease

Warnings and precautions

Talk to your doctor before you are given Potassium Chloride 2.98% w/v and Sodium Chloride 0.9% w/v Solution for Infusion.

Special care is necessary:

- if you have high levels of sodium in your blood (hypernatraemia)

- if you have any other condition where your sodium intake must be low, like heart failure, swelling, water on your lungs, high blood pressure, pre-eclampsia (see section “Pregnancy and breast-feeding”) or severe kidney disease
- if you have a shock
- if you suffer from severe tissue damage, such as in burn injuries
- if you have too much water in your body (hyperhydration)

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

- 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 function:
You will receive this medicine as a slow intravenous drip after your doctor has made sure that your kidneys are working properly. If they don’t do so, your potassium blood levels and your ECG 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.

It will be made absolutely sure that the solution is administered into your vein in order to avoid tissue damage.

Your ECG, your fluid balance, the salts in your blood and your level of glucose will be checked regularly while you are receiving this medicine.

Children:

This medicine will be given to children only with special caution. In addition, their salt and fluid balance will be closely monitored.

Elderly patients, who are more likely to suffer from heart and kidney problems, will be closely monitored during treatment and the dosage will be carefully adjusted.

Other medicines and Potassium Chloride 2.98% w/v and Sodium Chloride 0.9% w/v

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

In particular, your doctor will pay attention to:

Medicines for treatment of heart weakness (digoxin, cardiac glycosides):

The effects of these medicines will become weaker when the blood potassium level rises. They will become stronger (possibly with irregular heartbeat) when your blood potassium level decreases.

Medicines that contain potassium or may lead to high potassium levels in your blood, such as:

- potassium-sparing medicines e.g. spironolactone or triamterene (medicines that increase urine flow)
- ACE inhibitors (medicines to treat high blood pressure or heart failure)
- AT₁-receptor antagonists (a type of antihypertensive medicine)
- non-steroidal anti-inflammatory agents (medicines used as painkillers or to treat inflammation)

- cyclosporine, tacrolimus (medicines that are used after an organ transplant)
- suxamethonium (a medicine that is used during anaesthesia)
- aliskiren (a medicine used to treat high blood pressure)

Your doctor will take special care of you if you receive/take medicines that make you retain potassium as these may lead to heart problems (cardiac arrhythmia).

Medicines that may lead to a decrease of potassium level in your blood:

If you are taking certain medicines, namely corticosteroids, amphotericin B, ACTH and loop diuretics, your renal elimination of potassium can be increased.

Medicines causing sodium retention:

Your doctor will take care if you use medicines that make you retain sodium such as corticosteroids and non-steroidal anti-inflammatory agents because these may lead to swelling due to fluids (oedema).

Pregnancy and breast-feeding

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

Your doctor will administer Potassium Chloride 2.98% w/v and Sodium Chloride 0.9% w/v Solution for Infusion to you only with caution and when clearly needed.

Driving and using machines

This medicine has no influence on the ability to drive or use machines.

3. How to use Potassium Chloride 2.98% 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.

Dosage

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 ECG will be checked regularly. Your doctor will make sure that your urine flow is sufficient.

This medicine may be given to you as long as you need potassium by an infusion.

Children and adolescents:

In children and adolescents, the dose will depend upon the individual needs. They may receive a reduced dose.

Elderly patients:

In principle, the same dose as for adults can be used. However, in older people it might be necessary to adjust the dose stated to avoid circulatory and kidney problems.

Method of administration

This medicine will be administered to you through a tube placed into a vein (intravenous drip).

If you receive more Potassium Chloride 2.98% 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 an impairment of your kidney function you may experience disorders of your electrolyte levels, water and acid-base balance. You may also experience tissue fluid accumulation and potassium intoxication.

Potassium blood levels may especially be excessively increased. Signs of such disorder may be:

- Low blood pressure (hypotension)
- Irregular heartbeats 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 your sodium level increases too rapidly your brain may become damaged (osmotic demyelination syndrome). 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. Additionally, you may be given medicines that increase your urine flow. Your ECG will be monitored continuously. Your doctor will decide on further medication such as insulin or other measures to normalise your electrolyte levels, water balance and acid-base balance.

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.

The following side effects may be serious. If any of the following side effects occur, consult a doctor immediately

- irregular heartbeat (cardiac arrhythmia, the result of abnormally high administration rates)

Other side effects

- pain or tenderness, irritation or inflammation of veins (thrombophlebitis) at the site of injection

The frequency at which these side effects may occur is not known (frequency cannot be estimated from the available data).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Potassium Chloride 2.98% w/v and Sodium Chloride 0.9% w/v

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 label and the carton. The expiry date refers to the last day of that month.

For 50 ml plastic bags: Store below 25°C.

For 100 ml plastic bags: This medicinal product does not require any special precautions for storage.

Do not freeze.

Only to be used if the solution is clear, colourless and the container and its closure are undamaged.

This container is for single use only. After use discard container and any remaining contents.

6. Contents of the pack and other information

What Potassium Chloride 2.98% w/v and Sodium Chloride 0.9% w/v contains

- The active substances are potassium chloride and sodium chloride.
1 ml of solution for infusion contains 29.8 mg potassium chloride and 9 mg sodium chloride.
1000 ml of solution for infusion contains 400 mmol potassium, 154 mmol sodium and 554 mmol chloride.
- The other ingredients are:
water for injections
hydrochloric acid and sodium hydroxide for pH adjustment

What Potassium Chloride 2.98% w/v and Sodium Chloride 0.9% w/v looks like and contents of the pack
Potassium Chloride 2.98% w/v and Sodium Chloride 0.9% w/v is a clear, colourless solution of potassium chloride and sodium chloride in water.

It comes in plastic bags sealed in an overwrap containing 50 ml or 100 ml, supplied in packs of 20 x 50 ml and 20 x 100 ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer responsible for batch release

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

Postal address
34209 Melsungen, Germany

Tel.: +49/5661/71-0
Fax: +49/5661/71 4567

Manufacturer

B. Braun Medical AG
Route de Sorge 9
1023 Crissier, Switzerland

The leaflet was last revised in: 10/2024

The following information is intended for healthcare professionals only:

Potassium Chloride 2.98% w/v and Sodium Chloride 0.9% w/v must be administered by slow intravenous infusion via a central venous route using an infusion pump.

Method of administration:

Potassium Chloride 2.98% w/v and Sodium Chloride 0.9% w/v must be used only via a central venous route. Slow intravenous infusion at a rate normally not exceeding 20 mmol potassium per hour using an infusion pump.

In urgent cases where the serum potassium level is less than 2.0 mmol/l or where severe hypokalemia is a threat, rates up to 40 mmol per hour or 400 mmol over a 24 hour period can be administered very carefully when infused via a central vein to diminish the risk of causing sclerosis and when guided by continuous monitoring of the ECG and frequent serum K⁺ determinations to avoid hyperkalemia and cardiac arrest. Ensure that the catheter is not in the atrium or ventricle to avoid localized hyperkalaemia.

As a matter of principle, infusion pumps should be used for the infusion of potassium in the setting of correction therapy.

Posology:

Adults:

The following recommendations are general guidelines on potassium.

- Potassium

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

$$\text{mmol K}^+\text{required} = (\text{body weight [kg]} \times 0.2)^* \times 2 \times (\text{serum-K}^+\text{target}^{**} - \text{serum-K}^+\text{actual [mmol/l]})$$

*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.

Infusion rate

The infusion rate will depend on the conditions of the individual patient. Generally, the maximum potassium substitution rate is 20 mmol per hour.

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

Paediatric population

Generally, a substitution rate of 0.5 mmol/kg potassium BW per hour should not be exceeded.

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.

Special warnings and precautions:

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.

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.

Potassium Chloride 2.98% w/v and Sodium Chloride 0.9% w/v is hypertonic. The administration of a substantially hypertonic solution may lead to a variety of complications such as crenation (shrinkage) of red blood cells and general cellular dehydration. It should be administered with care in patients with hypertonic dehydration.

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:

This medicinal product must not be mixed with other medicinal.

Shelf life after addition of additives:

Not applicable.

For complete information on this medicinal product please refer to the summary of product characteristics.