

PACKAGE LEAFLET: INFORMATION FOR THE USER

B. Braun Melsungen AG · 34209 Melsungen, Germany

Sterile Potassium Chloride Concentrate (15% w/v) BP

Potassium chloride

Read all of this leaflet carefully before you receive 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.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Sterile Potassium Chloride Concentrate (15% w/v) BP is and what it is used for
2. What you need to know before you use Sterile Potassium Chloride Concentrate (15% w/v) BP
3. How to use Sterile Potassium Chloride Concentrate (15% w/v) BP
4. Possible side effects
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1. What Sterile Potassium Chloride Concentrate (15% w/v) BP is and what it is used for

Sterile Potassium Chloride Concentrate (15% w/v) BP is a concentrated solution of potassium chloride.

It is used to supply potassium to you

- when you have a deficit of potassium, especially if it is accompanied by excess alkali and abnormally low chloride levels in your blood (hypochloraemic alkalosis).
- as part of parenteral nutrition, when you are unable to eat food normally.

2. What you need to know before you use Sterile Potassium Chloride Concentrate (15% w/v) BP

Do not use Sterile Potassium Chloride Concentrate (15% w/v) BP:

- if you have an abnormally high potassium or chloride level in your blood (hyperkalaemia, hyperchloraemia)

Warnings and precautions

Talk to your doctor before using Sterile Potassium Chloride Concentrate (15% w/v) BP.

Special care with Sterile Potassium Chloride Concentrate (15% w/v) BP is necessary

- if you have heart problems
- if you have a disease where the potassium excretion in the urine is often reduced, such as impaired kidney function, Addison's disease (a specific disease of the adrenal gland), or sickle cell anaemia (an inherited disease of the red blood cells). If your kidney function is severely impaired or if you are on dialysis, your doctor will consult a kidney specialist before giving you this medicine
- if you are taking or receiving medicines that reduce potassium excretion in urine. For example if you are taking:
 - certain medicines increasing urine flow (diuretics)
 - certain blood pressure medications (Angiotensin II receptor antagonists, ACE inhibitors)
- if you have shock (an acute medical condition accompanied with a fall in your blood pressure, cold skin, rapid heart beat, and irregular breathing which can occur e.g after you have lost a lot of blood, you have experienced severe burns, you have had an allergic reaction)
- if you suffer from severe tissue damage, such as in burn injuries
- if you suffer from a disorder that causes muscle weakness and sometimes a higher than normal level of potassium in the blood (hyperkalaemic familial periodic paralysis)

Your doctor will take these points into consideration before and during your treatment with this medicine.

If you receive this medicine because you are lacking potassium, you will at first receive no glucose infusion at the same time because glucose may further decrease your potassium levels.

- While you are receiving this medicine your blood electrolyte levels and the acid-base balance will be monitored. This will be done to ensure that these are normal. Furthermore, your ECG might be monitored.
- It will be made absolutely sure that the solution is administered into your vein in order to avoid tissue damage.

If you receive this medicine because you are lacking potassium, your doctor will usually give it to you using an infusion pump.

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.

If you are very undernourished, i.e. you have not been receiving enough food, there is a chance that you may suffer from a condition called "Refeeding syndrome". Your doctor will monitor you carefully and only increase your nutrient intake slowly.

Other medicines and Sterile Potassium Chloride Concentrate (15% w/v) BP

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

In particular, your doctor will have to pay attention to:

- Medicines for treatment of heart weakness (cardiac glycosides, e.g. digoxin):

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 lower the potassium excretion in urine:

This group of medicines includes

- some medicines increasing the urine flow (potassium-saving diuretics like triamterene, amiloride, spironolactone),
- certain medicines for treatment of high blood pressure (Angiotensin II receptor antagonists or ACE inhibitors)
- medicines that suppress your immune system (tacrolimus, ciclosporin)
- certain medicines used as painkillers or to treat inflammation (non-steroidal anti-inflammatory drugs)

–blood thinning medicines (heparin)

Giving potassium together with these may lead to very high blood potassium levels. This may affect your heart rhythm.

Medicines that increase the potassium excretion in urine:

The following medicines can increase the potassium excretion in urine:

- a certain hormone (adrenocorticotrophic hormone [ACTH])
- certain medicines to treat inflammation (corticosteroids)
- some medicines increasing the urine flow (loop diuretics)

Giving potassium together with these may lead to you receiving the wrong dose of potassium as the potassium given to you will be lost from your body more quickly than normal.

- Suxamethonium (a muscle relaxing agent used in general anaesthesia):

Giving potassium together with this may also lead to very high blood potassium levels. This may affect your heart rhythm.

Pregnancy and breast-feeding

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

Pregnancy

Up to now there are no reports about damaging effects or risks associated with the use of this medicine in pregnant women..

Your doctor will administer potassium chloride to you only with caution and when clearly needed.

Breast feeding

Potassium chloride concentrate for infusion may be used during breast-feeding.

Driving and using machines

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

3. How to use Sterile Potassium Chloride Concentrate (15% w/v) BP

Sterile Potassium Chloride Concentrate (15% w/v) BP is administered to you after dilution in a suitable solution. It is given through a cannula or small tube into a vein (intravenous infusion).

Dosage

The amount you are to receive is calculated by your doctor, based on your acid-base balance, your age and your individual requirements.

If you use more Sterile Potassium Chloride Concentrate (15% w/v) BP than you should

It is unlikely that you will ever receive too much of the medicine. Your doctor or healthcare professional will monitor the application.

Symptoms

Overdose may lead to abnormally high potassium levels with the adverse effects listed below. Adverse effects are more likely to occur when you suffer from a shift of your blood to the acidic side (acidosis) or disorders of your kidneys.

Heart and circulation:

- slow heartbeat or even heart stoppage
- changes in the electrocardiogram
- drop of blood pressure
- re-distribution of circulating blood from limbs to head and trunk.

Muscles and nerve system:

- weakness,
- fatigue,
- states of confusion,
- heaviness of limbs,
- muscle twitching,
- loss of feeling,

- paralysis.

Treatment

If an overdose occurs the infusion will be stopped immediately and your doctor will give you any necessary treatment.

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

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.

- accumulation of acidic substances in the blood (acidosis) (frequency not known)
- abnormally high chloride blood levels (hyperchloraemia) (frequency not known)
- irregular heart beat (cardiac arrhythmia, the result of abnormally high administration rates) (frequency not known).

Other side effects

- feeling sick (nausea) (frequency not known)
- reactions at the injection site, including local pain, irritation or inflammation of veins (thrombophlebitis) and escape of fluid into the tissue (extravasation) (frequency not known)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

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 the package 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 Sterile Potassium Chloride Concentrate (15% w/v) BP

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.

Do not store above 25°C.

No special requirements for disposal.

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

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The medicine is supplied in single-use containers. After use, throw away the container and any unused content.

6. Contents of the pack and other information

What Sterile Potassium Chloride Concentrate (15% w/v) BP contains

- The active substance is potassium chloride
1 ml solution contains
150 mg potassium chloride.
corresponding to 2 mmol potassium and 2 mmol chloride

One 10 ml ampoule contains 1.50 g potassium chloride
- The other ingredient is:
water for injections

What Sterile Potassium Chloride Concentrate (15% w/v) BP looks like and contents of the pack

Sterile Potassium Chloride Concentrate (15% w/v) BP is a concentrate for the production of a solution for infusion. It must be diluted before use and is administered by an intravenous drip.

It is a clear, colourless aqueous solution.

Sterile Potassium Chloride Concentrate (15% w/v) BP is available in

- polyethylene plastic ampoules, contents: 10 ml in packs of 20 × 10 ml

Marketing Authorisation Holder and Manufacturer

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The following information is intended for healthcare professionals only:

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