

Package leaflet: Information for the patient
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 nurse.

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Potassium Chloride 15% w/v Concentrate for Solution for Infusion, it will be referred to as Potassium Chloride Concentrate throughout the leaflet for ease here after.

What is in this leaflet:

1. What Potassium Chloride Concentrate is and what it is used for
2. What you need to know before you are given Potassium Chloride Concentrate
3. How you are given Potassium Chloride Concentrate
4. Possible side effects
5. How to store Potassium Chloride Concentrate
6. Contents of the pack and other information

1. WHAT POTASSIUM CHLORIDE CONCENTRATE IS AND WHAT IT IS USED FOR

Potassium Chloride Concentrate belongs to a group of medicines called electrolyte replacement solutions. Electrolytes are a group of chemicals and salts that are in the body fluids. Potassium Chloride Concentrate is used in patients needing additional amounts of potassium.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN POTASSIUM CHLORIDE CONCENTRATE

You should not be given Potassium Chloride Concentrate if :

- you know that you are allergic to potassium chloride or any of the other ingredients in this medicine (listed in section 6)
 - you have high levels of potassium in your blood (hyperkalaemia)- your doctor will advice you.
- Make sure your doctor knows if you suffer from the above.

Warnings and precautions

Talk to your doctor or nurse before you are given Potassium Chloride Concentrate if you:

- have a kidney disorder or if your adrenal glands are not working properly (your doctor will advise you)
- have heart disease

- have had a recent severe injury involving a large area of skin such as a burn.
- Make sure your doctor is aware of these situations if it is not already obvious.

Other medicines and Potassium Chloride Concentrate

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

In particular, tell your doctor if you are taking any of the following:

- Diuretics (“water tablets”)
- Other medicines containing potassium (e.g. triamterene, spironolactone).

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 taking this medicine.

Do not have Potassium Chloride Concentrate if you are pregnant (or think you may be), or breast feeding unless your doctor has decided that it is in your best interests.

Driving and using machines

Potassium Chloride Concentrate should not interfere with your ability to drive or use machines but consult your doctor first.

3. HOW YOU ARE GIVEN POTASSIUM CHLORIDE CONCENTRATE

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

Potassium Chloride Concentrate is diluted and then slowly dripped through a needle into a vein. The process may take an hour or more depending on your dose. Your doctor will decide the best dose for you.

While this medicine is being injected, your ECG (electrocardiogram, measuring the heart) should be monitored continuously.

If you are given more Potassium Chloride Concentrate than you should

As Potassium Chloride Concentrate is administered by a healthcare professional it is unlikely that you will be given too much. If you think you have been given too much medicine, tell your doctor. The likely signs of an overdose are the occurrence of side-effects as listed below. In this event, you will be treated in the hospital and you will be given the necessary treatment.

If you miss a dose of Potassium Chloride Concentrate

This is unlikely as the infusion is given by a healthcare professional but if you are concerned about missing a dose speak to your doctor.

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

4. POSSIBLE SIDE EFFECTS

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

The most likely side-effects are:

- Pain at the site of injection.
- Inflammation of the vein into which the solution is injected.

The following signs and symptoms are typically associated with an overdose:

- Tingling or other odd sensations
- Muscle weakness or loss of movements
- Faintness or irregular heart beats, or heart attack
- Too much potassium in the blood (hyperkalaemia) which would be identified by a blood test
- Low blood pressure causing dizziness on standing (hypotension).

Please tell your doctor as soon as possible if you experience any of the above or are concerned they may have occurred.

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

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 HPRa Pharmacovigilance.

Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE POTASSIUM CHLORIDE CONCENTRATE

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

Do not use Potassium Chloride Concentrate after the expiry date which is stated on the carton and the ampoule label after 'Exp'. The expiry date refers to the last day of that month.

Do not store above 25°C. Keep the ampoule in the outer carton in order to protect from light.

For single use only.

Dilute immediately after opening with not less than 50 times its volume of Sodium Chloride Injection or another suitable diluent and use the diluted product immediately. If only part used, discard the remaining solution.

Do not use the solution if the ampoule is damaged or if the contents are discoloured in any way or contains particles in it.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Potassium Chloride Concentrate contains

The active substance is Potassium Chloride. Each 10ml of sterile concentrate for solution for infusion contains 15% w/v (1.5g) potassium chloride equivalent to approx. 20 millimoles of K⁺ and Cl⁻ ions in water for injections (150mg in 1ml).

What Potassium Chloride Concentrate looks like and contents of pack

Potassium Chloride Concentrate is a clear, colourless, sterile concentrate for solution for infusion. Potassium Chloride Concentrate is supplied in pack of 10 ampoules.

Marketing Authorisation Holder

Mercury Pharmaceuticals (Ireland) Ltd., 4045, Kingswood Road, City West Business Park, Co Dublin, Ireland.

Manufacturer

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