Package leaflet: Information for the patient

Potassium Chloride 15% w/v Concentrate for Solution for Infusion

potassium chloride

Please read all of this leaflet carefully. It includes important information on how you should take this medicine correctly and safely.
- Keep this leaflet. You may need to read it again.
- If you are the parent of a child who is to be given this medicine, read the leaflet replacing
- 'you' with 'your child' throughout.
- This medicine is prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or you notice any side effects not listed in the leaflet, please tell your doctor, nurse or pharmacist.
- If you have any further questions, please ask your doctor, nurse or pharmacist.

The name of your medicine is Potassium Chloride 15% w/v Concentrate for Solution for Infusion.
In the rest of this leaflet Potassium Chloride 15% w/v Concentrate for Solution for Infusion is called Potassium Chloride.

What is in this leaflet:
1. What Potassium Chloride is and what it is used for
2. Before you take Potassium Chloride
3. How to take Potassium Chloride
4. Possible side effects
5. How to store Potassium Chloride
6. Further information

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

Potassium Chloride is a type of medicine called an electrolyte. Electrolytes help keep the water levels in different parts of your body in the right balance. Potassium Chloride works by replacing a substance called potassium that your body has lost. Your body needs the right amount of potassium. Potassium helps your muscles, heart and other organs to work properly. Potassium also helps balance the water levels that affect many electrical and chemical processes in your body. Without the right amount of potassium your heart may start to beat abnormally, which could be life-threatening.
If you cannot take potassium by mouth, your doctor or nurse will give you this medicine as a drip (infusion).

2. Before you take Potassium Chloride

The doctor or nurse giving you this medicine will ask some questions about you. They need the following information before you have this medicine for the first time.

Do not take Potassium Chloride
- If you have hyperkalaemia (high levels of potassium in your blood).

Do not take Potassium Chloride if the above statement is true.

Take special care with Potassium Chloride
Tell your doctor or nurse before your treatment starts if:
- You have problems with your kidneys or adrenal glands
- You have problems with your heart
- You have been told you are very dehydrated (you do not have enough water in your body)
- You have heat cramps
- You have a lot of your skin damaged (such as extreme burns)
- You are elderly (over 65 years old)
- You have problems passing urine
- You are having a drip (infusion) containing the sugar called glucose.

Taking other medicines
Please tell your doctor about any medicines you may be taking or have recently been taking. Remember also any medicines you may be taking that do not need a prescription.

If you are taking any of the following medicines it is very important to tell your doctor:
- ACE inhibitors such as lisinopril, captopril, enalapril (may make the amount of potassium in your blood too high)
- Angiotensin-II receptor antagonists such as losartan, valsartan, candesartan (may make the amount of potassium in your blood too high)
- Blood transfusion (may make the amount of potassium in your blood too high)
- Ciclosporin (may make the amount of potassium in your blood too high)
- Corticosteroids such as cortisone, hydrocortisone, prednisone, prednisolone, betamethasone (may make your potassium chloride not work properly)
- Digoxin (may give you more side effects)
- Potassium-sparing diuretics such as spironolactone (may make the amount of potassium in your blood too high)
- Quinidine (may make your heart start to beat abnormally)
- Tacrolimus (may make the amount of potassium in your blood too high).

Taking salt-substitutes
If you are using potassium-containing salt substitutes in your diet, you must tell your doctor. You may be getting too much potassium if you take this medicine at the same time.

Pregnancy and breast-feeding
- If you are pregnant, or think you may be pregnant you must tell your doctor.
- If you are breast-feeding you must tell your doctor.

Your doctor will advise you if you should have this medicine.

3. How to take Potassium Chloride

Potassium chloride must be diluted before use at least 50 times its volume with a suitable diluent.
A doctor or a nurse will usually give you this medicine. Your doctor or nurse will give you the correct dose as a drip into your vein (your doctor or nurse may call this an IV or intravenous infusion).

Please read the other side of this leaflet.

Your doctor will decide the amount (dose) of your medicine that you should receive and how long you will need to take it for. Your doctor will also decide the strength of the medicine to give to you. The medicine is very strong, and must always be made weaker by adding more liquid (diluting) before you receive it.
Your doctor will monitor your heart while you receive your medicine. Your doctor will also take some blood tests, and check the amount of urine you make. This is to check the amount of potassium in your blood while you are having your medicine. If you have a very low amount of potassium in your blood, or you have diabetic ketoacidosis (a complication of diabetes), you may receive the medicine more quickly than usual.

Adults and the elderly
The usual dose is up to 80 mmol (millimoles) per day. The medicine will be made at a strength of 20 - 40 mmol/litre.

Infants and children
The usual dose is up to 3 mmol (millimoles) per kg of bodyweight per day. The medicine will be made at a strength of 20 mmol/litre. For children weighing 25kg or over, refer to the adult dosage.

If you take more Potassium Chloride than you should
A doctor or a nurse will usually give you this medicine. If you think you may have received too much medicine, please tell your doctor or nurse at once. Too much potassium in your blood will cause serious side effects that may be life-threatening. Please read carefully the important advice at the beginning of the next section, Section 4, about how you can spot the signs of too much potassium in your blood.

If you forget to take Potassium Chloride
A doctor or a nurse will usually give you this medicine. If you think you have missed a dose, please tell your doctor or nurse.
If you have any further questions on the use of your medicine, ask your doctor, nurse or pharmacist.

4. Possible side effects

Like all medicines, Potassium Chloride can cause side effects, but not everyone gets them. The expected benefit of your medicine will usually be greater than the risk of you suffering any harmful side effects.

Important: Side effects or symptoms to look out for, and what to do if you are affected. The first signs of having too much potassium in your blood are abnormal heartbeats, chest pain, possible heart attack, muscle weakness, paralysis or difficulty breathing. If you get any of these symptoms you must seek urgent medical advice.

The following other side effects may occur in some people:

Immune system problems:
- Fever.

Heart and circulation problems:
- Low blood pressure (you may feel light-headed).

Infusion site problems:
- Pain, redness, soreness and swelling at the site of the drip.

Nervous system problems:
- Prickling or tingling of the hands or feet
- Paralysis where the muscles are floppy
- Loss of reflexes
- Weakness, lack of energy
- Mental confusion
- Weakness and heaviness of legs.

If any of these side effects gets serious, or if you notice any troublesome symptoms which you think may be side effects, please tell your doctor, nurse 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 Yellow Card Scheme, Website: 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

Keep your medicine out of the reach and sight of children. Do not use your medicine after the expiry date (EXP) given on the carton and the label on the plastic container (ampoule). The expiry date is the last day of the month written on the packaging. This medicinal product does not require any special storage conditions.
Only use your medicine if it is a clear and colourless liquid. Open it and use it straight away. The product should be diluted and used immediately after opening. Any unused product should be discarded.
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. Further information

What Potassium Chloride contains
The active medicine is Potassium Chloride. The other ingredient is Water for Injections.
The medicine contains 15 % w/v (150 mg per ml) of Potassium Chloride. Each ml (millilitre) of this medicine contains 2 mmol of potassium and 2mmol chloride.

What Potassium Chloride looks like
Potassium Chloride is a concentrate for solution for infusion. This means it is a concentrated (strong) solution in a plastic container. It is a clear, colourless liquid. Potassium chloride must be diluted before use at least 50 times its volume with a suitable diluent. The solution must have more liquid added (diluted) to make a weaker solution that can then be given to you as a drip (an infusion).

Contents of the pack
Each plastic ampoule will contain 5 ml (millilitres), 10 ml or 20 ml of your medicine. 20 ampoules come in a box. Not all pack sizes may be available.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Noridem Enterprises Limited,
Evagorou and Makariou, Mitsi Building 3, Office 115, Nicosia 1065, Cyprus

Manufacturer:
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This leaflet was last revised in 11/2025.