

PACKAGE LEAFLET: INFORMATION FOR THE USER

POTASSIUM CHLORIDE 0.3%w/v SODIUM CHLORIDE 0.18%w/v GLUCOSE 4%w/v SOLUTION FOR INFUSION

Potassium chloride, sodium chloride and glucose anhydrous

Read all of this leaflet carefully before being given 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.

What is in this leaflet

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1. WHAT POTASSIUM CHLORIDE 0.3%w/v SODIUM CHLORIDE 0.18%w/v GLUCOSE 4%w/v SOLUTION FOR INFUSION IS AND WHAT IT IS USED FOR

Potassium Chloride 0.3%w/v Sodium Chloride 0.18%w/v Glucose 4%w/v Solution for Infusion is a clear colourless to faintly straw-coloured solution of potassium chloride, sodium chloride and glucose in water. The solution is stored in a sealed flexible plastic bag.

Potassium, sodium and chloride ions are important for maintaining the correct balance of fluid in and around the body's cells and tissues, and are involved in nerve signals and muscle contractions. Glucose is a simple sugar which provides a source of energy. The solution is given to help restore the normal salt balance, to add water to tissues which are dehydrated and to provide energy.

The solution may be given alone but may be given with other medicines added.

You will be given Potassium Chloride 0.3%w/v Sodium Chloride 0.18%w/v Glucose 4%w/v Solution for Infusion in hospital by a doctor or nurse.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN POTASSIUM CHLORIDE 0.3%w/v SODIUM CHLORIDE 0.18%w/v GLUCOSE 4%w/v SOLUTION FOR INFUSION

You MUST NOT be given this solution if you have:

- an **allergy** to potassium chloride, sodium chloride or glucose or any of the other ingredients
- increased levels of **potassium, chloride** or **glucose** in the blood
- suffered a **stroke**
- just suffered a **head injury**
- severe **kidney disease**
- congestive **heart failure**
- **water retention**

Warnings and precautions

Talk to your doctor or nurse if you:

- have **heart, kidney** or **liver disease**, or **oedema** (swelling)
- are **dehydrated** which may cause thirst, dry mouth, dark urine, irregular heart beat, tiredness
- have **diabetes mellitus**
- have **high blood pressure**
- have severe **tissue destruction** such as occurs with burns
- are **very young** or **elderly**.

Other medicines and Potassium Chloride 0.3%w/v Sodium Chloride 0.18%w/v Glucose 4%w/v Solution for Infusion

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

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

- the **water tablets** spironolactone and triamterene (diuretics used in congestive heart failure)
- medicines for the treatment of **high blood pressure** (ACE inhibitors)
- **ciclosporin** or **tacrolimus** (immunosuppressants)
- **corticosteroids** used to treat inflammation.

Pregnancy, breast-feeding and fertility

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

The solution should be administered with care during pregnancy and breast-feeding, and to pregnant women with pre-eclampsia to avoid extreme levels of glucose or potassium in the mother and the foetus or baby.

Driving and using machines

The solution has no effect on your ability to drive or use machines.

3. HOW POTASSIUM CHLORIDE 0.3%w/v SODIUM CHLORIDE 0.18%w/v GLUCOSE 4%w/v SOLUTION FOR INFUSION IS GIVEN

The solution will be given to you in hospital.

You will receive the solution by infusion into a vein probably in your arm or your neck, administered by a doctor or nurse. The amount and rate at which the infusion is given depends on your requirements, but usually 500ml is given over 2-3 hours. Your doctor will decide on the correct volume for you to receive.

Your doctor will check your response to the treatment by the relief of your symptoms, and will probably take samples of blood and urine for laboratory testing. Your heart function may be monitored.

If you are given more solution than you should

It is unlikely you will be given too much solution as your doctor or nurse will be checking your response to the treatment. If too much solution is given or if it is infused too quickly, the levels of potassium, sodium and glucose in the body may become too high. If you are concerned about the volume of solution given, or are worried about any effects you notice, talk to your doctor or nurse.

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

4. POSSIBLE SIDE EFFECTS

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

The infusion should be stopped immediately if you experience an adverse reaction.

If you are given the solution for a long time, you may notice the following:

- irritation, swelling, redness and tenderness at the site of injection.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

E-mail: medsafety@hpra.ie

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

5. HOW TO STORE POTASSIUM CHLORIDE 0.3%w/v SODIUM CHLORIDE 0.18%w/v GLUCOSE 4%w/v SOLUTION FOR INFUSION

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

Do not store above 25°C. Do not freeze. Store in the original outer container (overwrap) to prevent moisture loss to the air. Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

The solution should only be used if it is clear and the container is not damaged. It should be used immediately on removal from the overwrap. For single use only. Any unused solution in the bag must be discarded.

Do not throw away any medicines via wastewater or household waste. The doctor or nurse will dispose of this medicine. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Potassium Chloride 0.3%w/v Sodium Chloride 0.18%w/v Glucose 4%w/v Solution for Infusion contains

The **active** substances are potassium chloride, sodium chloride and glucose anhydrous (glucose) as glucose monohydrate. Each litre of solution contains 3g potassium chloride, 1.8g sodium chloride and 40g glucose. Each litre contains 40mmol potassium, 30mmol sodium, 70mmol chloride and 222mmol glucose.

The **other** ingredient is water for injections.

What Potassium Chloride 0.3%w/v Sodium Chloride 0.18%w/v Glucose 4%w/v Solution for Infusion looks like and contents of the pack

Potassium Chloride 0.3%w/v Sodium Chloride 0.18%w/v Glucose 4%w/v Solution for Infusion is a clear, colourless to faintly straw-coloured solution. The solution is packaged in a plastic bag. It is available in sizes of 500ml and 1000ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

CARELIDE

Rue Michel Raillard

59420 MOUVAUX

FRANCE

Manufacturer

CARELIDE

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