PACKAGE LEAFLET: INFORMATION FOR THE USER

Potassium Chloride 0.2%, Sodium Chloride 0.18%, and Glucose 4% Solution for Infusion
Potassium Chloride 0.3%, Sodium Chloride 0.18%, and Glucose 4% Solution for Infusion
Potassium Chloride 0.15% Sodium Chloride 0.18% and Glucose 4% Solution for Infusion

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT POTASSIUM CHLORIDE, SODIUM CHLORIDE AND GLUCOSE SOLUTION FOR INFUSIONS ARE AND WHAT THAY ARE USED FOR

Potassium chloride and sodium chloride help to maintain the body's store of essential potassium, sodium, and chloride ions. Glucose is a simple sugar, which provides a source of energy.

These infusions are used to replace potassium in the body.

The names of these medicines are:
Potassium Chloride 0.2%, Sodium Chloride 0.18%, and Glucose 4% Solution for Infusion.
Potassium Chloride 0.3%, Sodium Chloride 0.18%, and Glucose 4% Solution for Infusion.
Potassium Chloride 0.15% Sodium Chloride 0.18% and Glucose 4% Solution for Infusion

In this leaflet the three solutions will collectively be referred to as Potassium Chloride, Sodium Chloride and Glucose Solution for Infusions.

2. WHAT POTASSIUM CHLORIDE, SODIUM CHLORIDE AND GLUCOSE SOLUTION FOR INFUSIONS ARE AND WHAT THAY ARE USED FOR

You should not receive Potassium Chloride, Sodium Chloride and Glucose Solution for Infusions if you have:

- a known allergy to Potassium Chloride, Sodium Chloride and Glucose Solution for Infusions or to one or more of the ingredients of Potassium Chloride, Sodium Chloride and Glucose Solution for Infusions mentioned in section 6 (for symptoms of an allergic reaction please refer to section 4).
- **Addison's disease**
- **Adrenal insufficiency** (where the adrenal glands do not produce enough hormones)
- **Kidney** disease
- **Oliguria** or a**nuria** (decreased or no urine production)
- **Hyperkalaemia** (high potassium levels)

- **Liver** disorder

Your doctor will check these.

Warning and precautions

Care should be taken when being administered with Potassium Chloride, Sodium Chloride and Glucose Solution for Infusions:

Tell your doctor if you:

- have **heart** disease.
- are **dehydrated** or have heat cramp.
- have **sickle cell** disease (a condition affecting the red blood cells)

Before you receive Potassium Chloride, Sodium Chloride and Glucose Solution for Infusions your doctor will give you a non-potassium containing solution to prevent kidney damage.
Your doctor will make sure that the intravenous infusion is carried out slowly.
Your doctor or nurse will ensure the solution is clear and free from particles before use.
Your blood potassium levels will be monitored, and you may have your heart monitored by electrocardiogram (ECG).

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
Inform your doctor if you take or have recently taken any of the medicines below:

- Potassium sparing diuretics (**water tablets** that preserve potassium)
- **Potassium containing** intravenous solutions.
- Digitalis (for **heart disease**)
- ACE-inhibitors (for **high blood pressure** or **heart disease**)
- Cyclosporine (a drug used **after organ transplant**)
- Amikacin (an **antibiotic**)
- Amphotericin (an **antifungal** treatment)
- Benzyl-penicillin (an **antibiotic**)
- Dobutamine (for **heart disease**)

Medicines leading to increased vasopressin effect e.g.:

- Medicines stimulating vasopressin release (e.g., chlorpropamide, clofibrate, carbamazepine, vincristine, selective serotonin reuptake inhibitors, 3,4-methylenedioxy-N-methamphetamine, ifosfamide, medicines to treat mental disorders, narcotics)
- Medicines potentiating vasopressin action (e.g., non-steroidal anti-inflammatory drugs, chlorpropamide, cyclophosphamide)
- Medicines acting as vasopressin, so called vasopressin analogues e.g.: Desmopressin, oxytocin, vasopressin, terlipressin

Other medicinal products increasing the risk of hyponatraemia including diuretics in general and medicines to treat epilepsy such as oxcarbazepine.

Pregnancy, breast-feeding and fertility.
You should tell your doctor if you are pregnant, if you think you are pregnant or you are planning to become pregnant or if you are breastfeeding. Your doctor will decide whether you should receive a Potassium Chloride, Sodium Chloride and Glucose Solution for Infusions

Driving and using machines
Potassium Chloride, Sodium Chloride and Glucose Solution for Infusions may affect your ability to drive or operate machinery. Potassium Chloride, Sodium Chloride and Glucose Solution for Infusions may cause listlessness, confusion, weakness, and cardiac arrest. Ask your doctor when it would be safe to drive or operate machines.

3. HOW YOU ARE GIVEN POTASSIUM CHLORIDE, SODIUM CHLORIDE AND GLUCOSE SOLUTION FOR INFUSIONS

Potassium Chloride, Sodium Chloride and Glucose Solution for Infusions will be given to you in hospital by healthcare professionals.

You will receive your medicine by infusion (IV drip).

Dosage

The amount and rate at which the infusion is given depends on your requirements. Your doctor will decide on the correct dose for you to receive.

Elderly

A reduced volume and rate of infusion may be necessary, particularly if you suffer from heart and/or kidney damage.

If you receive more Potassium Chloride, Sodium Chloride and Glucose Solution for Infusions than you should.

It is very unlikely that you will receive more infusion than you should. If you suspect an overdosage with a Potassium Chloride, Sodium Chloride and Glucose Solution for Infusions you should look for the symptoms/side effects described below in this leaflet. You should immediately inform your doctor describing the symptoms.

Posology

General advice

Fluid balance, glucose and salts along with other electrolytes found within your blood may need to be monitored before and during administration, especially if you are at risk of high blood pressure or kidney problems. Monitoring of your salt levels is important for this type of infusion solution (hypotonic fluid), as it may become very hypotonic after administration due to glucose utilization in the body.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines Potassium Chloride, Sodium Chloride and Glucose Solution for Infusions can cause side effects, although not everybody gets them.

All medicines can cause allergic reactions although serious allergic reactions are very rare. If you get any of the following symptoms after receiving this medicine, you should contact your doctor immediately:

- Skin rash
- Difficulty breathing
- Swelling of your face, lips tongue or throat.

It is unlikely that you will receive more of a Potassium Chloride, Sodium Chloride and Glucose Solution for Infusion than you should. In the case of an overdose, you may experience:

- low blood pressure (hypotension)
- irregular heartbeat
- sudden stop of heartbeat (cardiac arrest)

As a Potassium Chloride, Sodium Chloride and Glucose Solution for Infusion will be given to you in hospital by healthcare professionals you will be monitored closely.

The following side effects have also been reported:

- listlessness (having no energy)
- low blood pressure(hypotension)
- confusion
- ‘pins and needles’
- weakness
- high blood pressure
- irregular heartbeats and very rarely heart attack
- thrombosis (the formation of a clot) may occur in the vein where the

- infusion is given

The symptoms of thrombosis include:
- Pain, swelling and redness at the blood clot site
- An itchy rash at the clot site
- Warm skin around the clot
- a mild fever
- major veins that stand out from your skin
- headache, nausea, seizures, lethargy. This can be caused by a low level of sodium in the blood. When sodium levels in the blood become very low, water enters the brain cells and causes them to swell. This results in increased pressure in the skull and causes hyponatraemic encephalopathy.

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

Reporting of side effects
If you get any side effects, talk to your doctor or 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/yellow card or search for MHRA Yellow card in the Google Play or Apple Store.

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

5. HOW POTASSIUM CHLORIDE, SODIUM CHLORIDE AND GLUCOSE SOLUTION FOR INFUSIONS ARE STORED

Keep out of the sight and reach of children.
Your doctor and hospital pharmacist are responsible for the correct storage, use and disposal of Potassium Chloride, Sodium Chloride and Glucose Solution for Infusions.
Potassium Chloride, Sodium Chloride and Glucose Solution for Infusions should be stored between 2°C and 25°C.
The solutions must not be used after the expiry date shown on the label. The expiry date refers to the last day of that month.
Any solution remaining after treatment should be disposed of using the approved hospital procedures.

6. FURTHER INFORMATION

What Potassium Chloride, Sodium Chloride and Glucose Solution for Infusion contain:

The infusions contain potassium chloride, sodium chloride, glucose, water for injections, hydrochloric acid, and sodium hydroxide.
The three strengths are:

- Potassium Chloride 0.2%, Sodium Chloride 0.18%, and Glucose 4% Solution for Infusion.
- Potassium Chloride 0.3%, Sodium Chloride 0.18%, and Glucose 4% Solution for Infusion.
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What Potassium Chloride, Sodium Chloride and Glucose Solution for Infusions look like and contents of the pack.

Potassium Chloride, Sodium Chloride and Glucose Solution for Infusions are clear solution of potassium chloride, sodium chloride and glucose in water.

The solutions are contained in a sealed plastic container known as a Steriflex bag or freeflex bag.
All three strengths of solutions are available in 500 ml and 1000 ml bags.
Not all sizes may be marketed.

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For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

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