**Package Leaflet: Information for the user**

**Potassium Chloride 0.15% w/v and Glucose 5% w/v**
**Solution for Infusion**

Potassium chloride and glucose

**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 pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet:**


## 1. What Potassium Chloride 0.15% w/v and Glucose 5% w/v is and what it is used for

This medicine contains a solution of potassium chloride and glucose. It is administered to you through a tube placed into a vein (intravenous drip).

You will receive it to maintain or restore your potassium levels and to cover your basic energy requirements.

## 2. What you need to know before you use this medicine

**Do not use Potassium Chloride 0.15% w/v and Glucose 5% w/v**
• if you have too high levels of potassium or chloride in your blood (hyperkalaemia or hyperchloremia)
• if you have severe kidney disease
• if you have had a head injury (during the first 24 hours)
• if you have too much water in your body (hyperhydration)
• if you have too high blood sugar levels (hyperglycaemia)
• if you have recently suffered from a stroke

**Warnings and precautions**

Patients who are acutely ill, with pain, postoperative stress, infections, burns, nervous system, heart, liver and kidney diseases and patients who are on medicines increasing the effect of vasopressin (a hormone which regulates the amount of body fluids), when given this solution are at particular risk of developing abnormally low levels of sodium in the blood (acute hyponatraemia) which can lead to swelling of the brain (encephalopathy).

Children, women of childbearing potential and patients with serious brain conditions like meningitis (infection of the membranes surrounding the brain) or brain injury are at particular risk of severe and life-threatening brain swelling caused by an acute decrease in blood sodium levels.

Talk to your doctor before you are given Potassium Chloride 0.15 % w/v and Glucose 5% w/v.

Before or when giving you this medicine, your doctor will pay attention to the following:

- Kidney function:
  You will receive this medicine as a slow intravenous drip after your doctor has made sure that your kidneys are working properly. If you have problems with your kidneys, your potassium, blood levels and your ECG will be monitored while you receive this medicine. Your doctor will make sure to stop the infusion in case your condition worsens.

- Heart disease:
  If you suffer from heart disease, this medicine will be given to you with caution.

- Swelling of the lower limbs or water on your lungs (pulmonary oedema):
  If you have one of these conditions, special care should be taken if you will be given large amounts of this medicine.

- Levels of salts in your blood:

- Certain types of diabetes:
  This medicine will be given to you with caution
  - if you have diabetes
  - in other conditions where your body is unable to process sugars as normal (e.g. if you are taking certain medicines, see also section 'Other medicines and Potassium Chloride 0.15 % w/v and Glucose 5% w/v' below)

  Your blood sugar levels will be monitored.

- Blood transfusions
  You will not be given this medicine together with, immediately before or after blood through the same tubing.

- Too much potassium in your blood
  If you have a disease where potassium levels are too high in your blood such as Addison's disease (a specific disease of the adrenal gland).

- Burns
  If you have burns this medicine will be given to you with caution

- Dehydration
  If you are dehydrated this medicine will be given to you with caution

Your ECG, your fluid balance, the salts in your blood and your level of glucose will be checked regularly while you are receiving this medicine.

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.

**Children**

This medicine will be given your child only with special caution. In addition, their salt and fluid balance will be closely checked.
This medicine will be given to your child cautiously, if the salt levels, especially sodium, are too low. Your doctor will make sure to monitor your child's salt and fluid levels.

**Other medicines and Potassium Chloride 0.15% w/v and Glucose 5% w/v**
Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicine, especially the following medicines which increase the effect of vasopressin and the risk of a low sodium level (hyponatraemia):

- Carbamazepine and Oxcarbazepine used to treat epilepsy
- Vincristine and Ifosfamide used as anticancer treatments
- Cyclophosphamide to treat cancer and autoimmune diseases
- Selective Serotonin Reuptake Inhibitors (SSRIs) to treat depression
- Antipsychotics for mental health disorders
- Opioid pain killers to relieve severe pain
- Non-steroidal anti-inflammatory drugs (NSAIDs) to relieve mild to moderate pain and to treat inflammation in your body,
- Desmopressin for the treatment of diabetes insipidus (extreme thirst and the continuous production of large volumes of dilute urine)
- Oxytocin used during labour
- Vasopressin and terlipressin used to treat 'bleeding oesophageal varices' (enlarged veins in your food pipe caused by liver problems)
- Diuretics or water tablets (medicines which increase the amount of urine you excrete)

If you are taking digoxin or similar medicines that help your heart to work better, tell your doctor as it may change how they work. The amount of Potassium Chloride 0.15 % w/v and Glucose 5% w/v may have to be adjusted.

Also tell your doctor if you are taking medicines that contain potassium or may lead to high potassium levels, such as:

- potassium-sparing medicines e.g. spironolactone or triamterene (medicines that increase urine flow)
- ACE inhibitors (medicines to treat high blood pressure or heart failure)
- Angiotensin II receptor antagonists (a type of antihypertensive medicine)
- non-steroidal anti-inflammatory agents (for acute or chronic conditions of pain and inflammation)
- cyclosporine, tacrolimus (medicines that are used after an organ transplant)
- suxamethonium (a medicine that is used during anaesthesia).

**They will take special care of you if you receive/take medicines that make you retain potassium as these may lead to heart problems (cardiac arrhythmia).** If you are taking certain medicines, namely corticosteroids, ACTH and loop diuretics your renal elimination of potassium can be increased.

**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 using this medicine.

This medicine can be given while you are pregnant or breast-feeding if your doctor considers it necessary.

**Driving and using machines**
Potassium Chloride 0.15 % w/v and Glucose 5% w/v has no influence on the ability to drive or use machines.

## 3. How to use Potassium Chloride 0.15% w/v and Glucose 5% w/v

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

Dose
The recommended dose that you will be given will be determined by your doctor. It will depend on your age, weight and condition, especially if your heart or kidneys do not work properly. While you receive this medicine your blood glucose and electrolyte (salt) levels, water balance and ECG will be checked regularly. Your doctor will make sure that your urine flow is sufficient.

The recommended maximum dose for an adult is 40 ml/kg body weight/day. In cases where more potassium is needed, your doctor will take into consideration other strengths as well.

This medicine may be given to you as long as you need energy, salts and fluid by an infusion.

Elderly
In principle, the same dose as for adults can be used. However, in older people it might be necessary to adjust the dose stated to avoid circulatory and kidney problems.

Use in children and adolescents
In children and adolescents the dose will depend upon the individual needs. They may receive a reduced dose.

Method of administration
This medicine will be administered to you through a tube placed into a vein (intravenous drip).

**If you receive more Potassium Chloride 0.15% w/v and Glucose 5% w/v than you should**

It is unlikely that this occurs because your doctor will determine your daily dose.

Your doctor will monitor chemical and fluid balance, glucose and electrolyte levels (including sodium) in your blood before and during treatment, especially in patients with disrupted vasopressin release (a hormone which regulates the amount of body fluids) and in patients taking medicines increasing the action of vasopressin due to the risk of abnormal low sodium level in your blood (hyponatraemia).

*Signs of an overdose*
If you have received too much of this medicine you may experience disorders of your salt, sugar, water and acid-base balance. You may also experience tissue fluid accumulation and potassium intoxication.
Potassium blood levels may especially be excessively increased. Signs of such disorder may be:
- Low blood pressure (hypotension)
- Irregular heart beats or your heart stops beating
- ECG abnormalities up to the heart stops beating
- General weakness and listlessness

- Muscle weakness, inability to move
- Very marked numbness, weakness or heaviness of your legs
- Confusion.

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

## 4. Possible side effects

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

You may develop an imbalance in the level of fluid and of certain minerals in your body. You may develop low sodium (hyponatraemia), potassium, phosphate and magnesium blood levels.
Abnormally low sodium level in your blood can lead to a serious condition called hospital acquired hyponatraemia. It may cause irreversible brain damage and death due to the development of brain oedema (acute hyponatraemic encephalopathy). The symptoms of brain oedema include: headache, feeling sick (nausea), vomiting, seizures, tiredness and lack of energy.

When this medicine is used according to the directions, it is very unlikely that side effects occur.

Tell your doctor if you notice pain, tenderness or inflammation of blood clots at the site of injection.

**Reporting of side effects**
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the 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 0.15% w/v and Glucose 5% w/v

Unopened: Do not store above 25°C.

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

Do not use Potassium Chloride 0.15 % w/v and Glucose 5% w/v after the expiry date which is stated on the labels of the bottles and the carton. The expiry date refers to the last day of that month.

Do not use the product if the solution appears cloudy or discoloured, if you find particles in the solution or if the bottle and its closure are damaged.

This container is for single use only. After use discard container and any remaining contents.

The product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

**What Potassium Chloride 0.15% w/v and Glucose 5% w/v Solution for Infusion contains**
• The active substances are potassium chloride and glucose.

1 ml of solution for infusion contains 1.5 mg potassium chloride and 50 mg glucose.
1,000 ml of solution for infusion contains 20 mmol potassium and 20 mmol chloride.

• The other ingredient is water for injections.

- Energy 835 kJ/l ≙ 200 kcal/l
  Theoretical osmolarity 318 mOsmol/l
  pH approximately 3.5- 6.5

**What Potassium Chloride 0.15% w/v and Glucose 5% w/v Solution for Infusion looks like and contents of the pack**

Potassium Chloride 0.15% w/v and Glucose 5% w/v Solution for Infusionis a clear, colourless up to faintly straw-coloured solution of potassium chloride and glucose in water.

It comes in plastic (polyethylene) bottles containing 500 ml or 1,000 ml, supplied in packs of 10 x 500 ml and 10 x 1000 ml.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**
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**The following information is intended for healthcare professionals only:**

Posology

*Adults:*

The following recommendations are general guidelines on potassium, however prescribing should follow local guidelines.

Potassium

The amount required for correction of moderate potassium deficiency and in maintenance may be calculated according to the following formula:

| |
|---|
| mmol K+required = (body weight [kg] × 0.2)* × 2 × (serum-K+target** – serum-K+actual [mmol/l]) |

*Term represents the extracellular fluid volume

** should be 4.5 mmol/l

The maximum recommended dose of potassium is 2 – 3 mmol/kg body weight (b.w.)/24 h.

Maximum infusion rate
Up to 5 ml/kg body weight per hour, corresponding to 0.25 g glucose/kg body weight per hour and 0.1-0.2 mmol/kg/ body weight per hour potassium (for 0.15% w/v and 0.3% w/v, respectively).

*Paediatric population*
Generally a substitution rate of 0.5 mmol/kg potassium BW per hour should not be exceeded.

Maximum daily dose

The maximum recommended dose of potassium is 2 - 3 mmol/kg BW per 24 hours. In any case the limits for daily fluid intake must not be exceeded.

Method of administration

As a matter of principle, infusion pumps should be used for the infusion of potassium in the setting of correction therapy.

Special precautions and warnings

Solutions with low electrolyte content, especially sodium, should also be administered with care in patients with hyponatraemia.

Care should be taken to avoid a rapid marked decrease of the serum sodium level as this may be associated with the risk of osmotic central nervous damage.

*Paediatric population*
The infusion of hypotonic fluids together with the nonosmotic secretion of ADH (in pain, the post-operative state,nausea, vomiting,) may result in hyponatraemia.

Treatment of an overdose

Immediate interruption of the infusion, ECG monitoring, if necessary enhancement of urine flow and thus fluid and electrolyte excretion, administration of sodium bicarbonate and insulin. If insulin is given to increase cellular uptake of potassium, glucose should be given to avoid hypoglycaemia. In patients with persistent ECG abnormalities e.g. calcium gluconate may be administered to antagonize the cardiotoxic effects of potassium. Haemodialysis or peritoneal dialysis may be required in patients with renal insufficiency.

Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

Shelf life after first opening the container

From a microbiological point of view, unless the method of opening precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times

and conditions are the responsibility of the user.For complete information on this medicinal product please refer to the summary of product characteristics.