

PACKAGE LEAFLET: INFORMATION FOR THE USER

Potassium Chloride 0.3 % w/v, Sodium Chloride 0.18 % w/v and Glucose 4 % w/v Intravenous Infusion BP

Active substances: Potassium Chloride, Sodium Chloride, Glucose

Read all of this leaflet carefully before you start using 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 0.3 % w/v, Sodium Chloride 0.18 % w/v and Glucose 4 % w/v Intravenous Infusion BP is and what it is used for
2. Before you use this medicine
3. How to use this medicine
4. Possible side effects
5. How to store his medicine
6. Further information

1. WHAT POTASSIUM CHLORIDE 0.3 % W/V, SODIUM CHLORIDE 0.18 % W/V AND GLUCOSE 4 % W/V INTRAVENOUS INFUSION BP IS AND WHAT IT IS USED FOR.

This medicine is a solution for infusion, i.e. it is administered to you through a thin tube placed into a vein.

It will be given to you to maintain or restore your sodium, potassium, chloride and fluid levels and as a source of calories.

2. BEFORE YOU USE THIS MEDICINE

Do not use this medicine

if you have:

- abnormally high levels of potassium or chloride in your blood
- severe kidney disease
- acute stroke
- head injury (first 24 hours)
- swelling of the lower limbs, too much water in your body tissues (hyperhydration).

This container contains a significant volume of air. To avoid risk of air embolism, this product must not be administered by pressure infusion.

Take special care with this medicine

if you have:

- heart disease
- kidney problems
- liver disease

- certain types of diabetes
- severe diabetes or any other condition associated with glucose intolerance
- lung disease or congestion of or water on the lungs (pulmonary oedema)
- abnormally low levels of electrolytes (salts) in your blood.

Special caution and careful monitoring of salt and fluid levels is required when this medicine is to be administered to children.

Taking or using 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.

In particular tell your doctor, if you are taking any of the following medicines, so that the amount of Potassium Chloride 0.3 % w/v, Sodium Chloride 0.18 % w/v and Glucose 4 % w/v Intravenous Infusion BP can be adjusted accordingly:

- digoxin (a medicine used to treat heart weakness)
- corticosteroids e.g. hydrocortisone or prednisone, because these may lead to salt retention and reduction of glucose tolerance
- potassium-sparing water tablets, e.g. those containing spironolactone or triamterene, or other drugs that may lead to high potassium levels, such as certain medicines used to treat high blood pressure (so-called ACE inhibitors) cyclosporine or suxamethonium.

Pregnancy and breast-feeding

Pregnancy

If you think you are likely to be pregnant, tell your doctor immediately. This medicine can be given while you are pregnant if your doctor considers it necessary.

Breast-feeding

If you are breast-feeding, tell your doctor immediately.

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

Driving and using machines

This medicine has no influence in the ability to drive and to use machines.

3. HOW TO USE THIS MEDICINE

The medicine will be administered to you by infusion through a vein.

The amount of the medicine that you will be given will be determined by your doctor and will depend on your age, weight and clinical condition. While you receive this medicine your blood glucose, and electrolyte (salt) levels and water balance will be monitored routinely.

The normal maximum dosage for an adult is 40 ml/kg body weight/day. Children will receive a reduced dosage dependent upon their age.

You should not receive this medicine through the same infusion equipment as blood.

IF YOU RECEIVE MORE OF THIS MEDICINE THAN YOU SHOULD (OVERDOSE)

It is unlikely that this happens as your infusion will be controlled by a doctor or nurse.

Yet if overdose occurs, you may experience disorders of fluid balance and serum electrolytes, swelling and heart and circulation disorders. Further symptoms are described below (Section 4. Possible side effects).

The therapy to normalise your condition will be determined by your doctor. It may include stopping of the infusion and administration of suitable medicines to treat the symptoms observed. In extreme situations you may also need dialysis.

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 0.3 % w/v, Sodium Chloride 0.18 % w/v and Glucose 4 % w/v Intravenous Infusion BP cause side effects, although not everybody gets them.

If any of the following happen, tell your doctor immediately or go to the emergency department at your nearest hospital:

- difficulty in breathing
- sudden severe chest pain
- slowing or quickening of your heart beat
- low blood pressure (hypotension)
- bad fainting attacks, or collapse
- weakness, disturbances of muscle movement
- very marked numbness, swelling or heaviness of your limbs
- cold skin or grey pallor
- confusion.

Tell your doctor if you notice pain or tenderness at the site of injection.

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 the package leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

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

5. HOW TO STORE THIS MEDICINE

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

This medicine is for single use only. Discard any unused medicine.

Do not store above 25°C.

Do not use the medicine after the expiry date which is stated on the label and the outer carton

The expiry date refers to the last day of that month.

This medicine should be clear in appearance. Do not use if it is cloudy or if the container has been damaged.

6. FURTHER INFORMATION

What Potassium Chloride 0.3 % w/v, Sodium Chloride 0.18 % w/v and Glucose 4 % w/v Intravenous Infusion BP contains

- The active substances are Potassium Chloride, Sodium Chloride and Glucose
1000 ml contain
Potassium chloride 3.00 g
Sodium chloride 1.80 g
Glucose 40.00 g
(as glucose monohydrate)
- The other ingredient is
Water for injections

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

Potassium Chloride 0.3 % w/v, Sodium Chloride 0.18 % w/v and Glucose 4 % w/v
Intravenous Infusion BP is a solution for infusion, i.e. a solution to be administered by a vein drip.

It is a sterile, clear, colourless solution of aforementioned substances in water.

It comes on colourless polyethylene bottles of 500 ml or 1000 ml, each available in packs of 10 bottles.

Marketing Authorisation Holder and

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