Baxter

PACKAGE LEAFLET: INFORMATION FOR THE USER

Potassium Chloride 0.15 % w/v & Sodium Chloride 0.9% w/v Solution for Infusion BP

Active substances: potassium chloride and sodium chloride

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 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.

Throughout this leaflet, Potassium Chloride 0.15% w/v & Sodium chloride 0.9% w/v, Solution for Infusion will be called Potassium 0.15 & Sodium 0.9 Infusion.

In this leaflet:

1. What Potassium 0.15 & Sodium 0.9 Infusion is and what it is used for
2. What you need to know before you use Potassium 0.15 & Sodium 0.9 Infusion
3. How to use Potassium 0.15 & Sodium 0.9 Infusion
4. Possible side effects
5. How to store Potassium 0.15 & Sodium 0.9 Infusion
6. Content of the pack and other information

1. WHAT POTASSIUM 0.15 & SODIUM 0.9 INFUSION IS AND WHAT IT IS USED FOR

Potassium 0.15 & Sodium 0.9 Infusion is a solution of potassium chloride and sodium chloride in water. Potassium chloride and sodium chloride are chemical substances (often called “salts”) found in the blood.
Potassium 0.15 & Sodium 0.9 Infusion is used to prevent and treat:

- a loss of potassium from the body (potassium depletion, e.g. after treatment with certain diuretics [water tablets])
- a low level of potassium in the blood (hypokalaemia).

in situations that may cause sodium chloride and water loss including:

- when you cannot eat or drink, due to illness or after surgery
- pronounced sweating due to high fever
- extensive skin loss, as can occur in severe burns.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE POTASSIUM 0.15 & SODIUM 0.9 INFUSION

You must NOT receive Potassium 0.15 & Sodium 0.9 Infusion if you are suffering from any of the following conditions:

- if you are allergic to potassium chloride and sodium chloride or any other ingredients of this medicine (listed in section 6)
- higher levels of potassium in the blood than normal (hyperkalaemia)
- higher levels of chloride in the blood than normal (hyperchloraemia)
- higher levels of sodium in the blood than normal (hypernatraemia)
- severe kidney failure (when your kidneys do not work well and you require dialysis)
- uncompensated heart failure. This is heart failure that is not adequately treated and causes symptoms such as:
  - shortness of breath
  - swelling of the ankles
- Addison’s disease (poor function of the adrenal gland. The adrenal gland produces hormones that help to control the concentrations of the chemicals in the body).

Warning and precautions

Potassium 0.15 & Sodium 0.9 Infusion is a hypertonic (concentrated) solution. Your doctor will take this into account when calculating how much solution to give you.

Please tell your doctor if you have or have had any of the following medical conditions.

- any type of heart disease or poor heart function
- poor kidney function
- adrenocortical insufficiency (disease of adrenal gland affects hormones that control the concentration of chemicals in the body).
- a loss of water from the body (acute dehydration, e.g. from vomiting or diarrhoea)
- extensive tissue damage (as can occur in severe burns)
- if you are being treated with cardiac glycosides (also called cardiotonics), such as digitalis or digoxin. These medicines are used to treat heart disease. Regular monitoring of the level of potassium in the blood must be performed.
- high blood pressure (hypertension)
- build up of fluid under the skin, particularly around the ankles (peripheral oedema)
- build up of fluid in the lungs (pulmonary oedema)
- high blood pressure during pregnancy (pre-eclampsia)
- any other condition associated with sodium retention (when the body retains too much sodium), such as treatment with steroids (See also below "Taking other medicines").
- if you have a condition that could cause high levels of vasopressin, a hormone regulating fluid in your body. You may have too much vasopressin in your body because, for example:
  - you have had a sudden and serious illness
  - you are in pain
  - you have had surgery
  - you have infections, burns or brain disease
  - you have diseases linked to your heart, liver, kidneys or central nervous system
  - because you are taking certain medicines (see also below "Other medicines and 'Potassium 0.15 & Sodium 0.9 Infusion").

This may increase the risk of low levels of sodium in your blood and can lead to headache, nausea, seizures, lethargy, coma, swelling of the brain and death. Brain swelling increases the risk of death and brain damage. People who are at higher risk of brain swelling are:

- children
- women (particularly if you are of a fertile age)
- people who have problems with their brain fluid levels, for example, because of meningitis, bleeding in the skull or a brain injury.

When you are given this infusion, your doctor will take blood and urine samples to monitor:

- the amount of fluid in your body
- your vital signs
- the amount of chemicals such as sodium and potassium in your blood (your plasma electrolytes)
- the acidity of your blood and urine (your acid-base balance)
- your heart tracing (ECG).

Your doctor will take into account if you are receiving parenteral nutrition (nutrition given by infusion into a vein). During long term treatment with Potassium 0.15 & Sodium 0.9 Infusion you may need to be given extra nutrition.

Other medicines and Potassium 0.15 & Sodium 0.9 Infusion

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

It is particularly important that you inform your doctor if you are taking:

- cardiac glycosides (cardiotonics) used to treat heart failure, such as digitalis or digoxin.
- medicines that increase the concentration of potassium in the blood, such as:
  - potassium-sparing diuretics (certain water tablets, e.g. amiloride, spironolactone, triamterene)
  - angiotensin converting enzyme (ACE) inhibitors (used to treat high blood pressure)
  - angiotensin II receptor antagonists (used to treat high blood pressure)
  - cyclosporin (used to prevent rejection of a transplant)
  - tacrolimus (used to prevent rejection of a transplant and to treat some skin diseases)

- medicines that contain potassium (e.g. potassium supplements, salt substitutes containing potassium)

- corticosteroids (anti-inflammatory medicines).
- some medicines act on the hormone vasopressin. These may include:
  - anti-diabetic medication (chlorpropamide)
  - cholesterol medicine (clofibrate)
  - some cancer drugs (vincristine, ifosfamide, cyclophosphamide)
  - selective serotonin reuptake inhibitors (used to treat depression)
  - antipsychotics
  - opioids for severe pain relief medicines for pain and/or inflammation (also known as NSAIDs)
  - medicines that imitate or strengthen the effects of vasopressin such as desmopressin (used to treat increased thirst and urination), terlipressin (used to treat bleeding of the gullet) and oxytocin (used to induce labour)
  - anti-epileptic medication (carbamazepine and oxcarbazepine)
  - diuretics (water tablets).
- Caution is advised in patients treated with lithium. The removal of the chemicals sodium and lithium, by your kidneys, may be increased during administration of potassium 0.15 & Sodium 0.9 Infusion.

Potassium 0.15 & Sodium 0.9 Infusion with food and drink

You should ask your doctor about what you can eat or drink.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Tell your doctor if you are pregnant or breast-feeding.

Potassium 0.15 & Sodium 0.9 Infusion can be given during pregnancy. The amount you are given must be carefully controlled by your doctor.
If another medicine is to be added to your solution for infusion during pregnancy or breast-feeding you should:

- consult your doctor
- read the Package Leaflet of the medicine that is to be added.

Driving and using machines

Potassium 0.15 & Sodium 0.9 Infusion does not affect your ability to drive or use machines.

3. HOW TO USE POTASSIUM 0.15 & SODIUM 0.9 INFUSION

Potassium 0.15 & Sodium 0.9 Infusion will be given to you by a doctor or nurse. Your doctor will decide on how much you need and when it is to be given. This will depend on your age, weight, clinical and biological conditions and state of hydration (the amount of water in your body). The amount you are given may also be affected by other treatments you are receiving.

You should NOT be given Potassium 0.15 & Sodium 0.9 Infusion if there are particles floating in the solution or if the pack is damaged in any way.

The speed of infusion will be decided by your doctor.

If you require a large volume or rapid infusion of Potassium 0.15 & Sodium 0.9 Infusion, your doctor may monitor your ECG (heart tracing).

Potassium 0.15 & Sodium 0.9 Infusion will usually be given to you through a plastic tube attached to a needle in a vein. Usually a vein in your arm is used to give you the infusion. However, your doctor may use another method to give you the medicine.

Before and during the infusion, your doctor will monitor

- potassium
- the amount of fluid in your body
- the acidity of your blood and urine
- the amount of electrolytes in your body (particularly sodium, in patients with high level of the vasopressin, or are taking other medicines which increase the effect of vasopressin).

If you suffer from poor kidney function, you may receive a lower dose.
Any unused solution should be thrown away. You should NOT be given an infusion of Potassium 0.15/ & Sodium 0.9 Infusion from a bag that has been partly used.

If you take more Potassium 0.15 & Sodium 0.9 Infusion than you should

If you are given too much Potassium 0.15 & Sodium 0.9 Infusion (over-infusion), this may lead to the following symptoms:

- increase in levels of potassium in blood (hyperkalemia)
- pins and needles in the arms and legs (paresthesia)inability to breathe (respiratory paralysis)
- nausea, vomiting, abdominal pain
- low blood pressure
- muscle weakness
- an irregular heartbeat (cardiac arrhythmias)
- heart block (a very slow heartbeat)
- cardiac arrest (the heart stops beating; a life-threatening situation)
- fluid collection in the lungs making it difficult to breathe (pulmonary oedema)
- fluid collection under the skin, particularly around the ankles (peripheral oedema).

If you develop any of these symptoms you must inform your doctor immediately. Your infusion will be stopped and you will be given treatment depending on the symptoms.

If a medicine has been added to your Potassium 0.15 & Sodium 0.9 Infusion before over-infusion occurs, that medicine may also cause symptoms. You should read the Package Leaflet of the added medicine for a list of possible symptoms.

If you stop taking your Potassium 0.15 & Sodium 0.9 Infusion

Your doctor will decide when to stop giving you this infusion.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Potassium 0.15 & Sodium 0.9 Infusion can cause side effects, although not everybody gets them.

The side effects that may occur

- due to the administration technique include:
  - fever (febrile response)
  - infection at the site of infusion
  - local pain or reaction (redness or swelling at the site of infusion)
  - irritation and inflammation of the vein into which the solution is infused (phlebitis). This can cause redness, pain or burning and swelling along the path of the vein into which the solution is infused.
  - the formation of a blood clot (venous thrombosis) at the site of infusion, which causes pain, swelling or redness in the area of the clot
  - escape of the infusion solution into the tissues around the vein (extravasation). This can damage the tissues and cause scarring.
  - an excess of fluid in the blood vessels (hypervolaemia)
  - any allergic reaction
  - increase levels of potassium in the blood (hyperkalemia)
  - Low levels of sodium in the blood that may be acquired during hospitalization (nosocomial hyponatraemia) and related neurological disorder (acute hyponatraemic encephalopathy). Hyponatraemia can lead to irreversible brain injury and death due to cerebral oedema/swelling (see also in the section 2 “Warnings and precautions”).
  - high chloride level in blood or low bicarbonate levels in blood (acidosis hyperchloremic)
  - cardiac arrest.

If a medicine has been added to the solution for infusion, the added medicine may also cause side effects. These side effects will depend on the medicine that has been added. You should read the Package Leaflet of the added medicine for a list of possible symptoms.

Please tell your doctor or nurse if you notice any listed or unlisted side effects. If any side effects occur, the infusion must be stopped.

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 following routes:

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

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Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

Malta
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

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

5. HOW TO STORE POTASSIUM 0.15 & SODIUM 0.9 INFUSION

Keep out of the reach and sight of children.

Potassium 0.15 & Sodium 0.9 Infusion does not require special storage conditions.

Potassium 0.15 & Sodium 0.9 Infusion should NOT be given to you after the expiry date which figures on the bag. The expiry date refers to the last day of that month.

You should not be given Potassium 0.15 & Sodium 0.9 Infusion, if there are particles floating in the solution or if the unit is damaged in any way.

6. CONTENT OF THE PACK AND OTHER INFORMATION

What Potassium 0.15 & Sodium 0.9 Infusion contains

The active substances are:

- potassium chloride: 1.5 g per litre
- sodium chloride: 9 g per litre

The only other ingredient is water for injections

What Potassium 0.15 & Sodium 0.9 Infusion looks like and contents of the pack

Potassium 0.15 & Sodium 0.9 Infusion is a clear solution, free from visible particles. It is supplied in polyolefin/polyamide plastic bags (Viaflo). Each bag is wrapped in a sealed, protective, outer plastic overpouch.
The bag sizes are:

- 500 ml
- 1000 ml

The bags are supplied in cartons. Each carton contains one of the following quantities:

- 20 bags of 500 ml
- 10 or 12 bags of 1000 ml

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder for the United Kingdom:
Baxter Healthcare Ltd
Caxton Way, Thetford,
Norfolk, IP24 3SE
United Kingdom

Marketing Authorisation Holder for Ireland and Malta:
Baxter Holding B.V.
Kobaltweg 49,
3542CE Utrecht,
Netherlands

Manufacturers for Great Britain:
Baxter SA
Boulevard René Branquart, 80
7860 Lessines
Belgium

Baxter Healthcare Ltd.
Caxton Way,
Thetford Norfolk IP24 3SE
United Kingdom

Bieffe Medital Sabiñanigo
Ctra de Biescas, Senegüé
22666 Sabiñanigo (Huesca)
Spain

Manufacturers for Ireland:
Baxter SA
Boulevard René Branquart, 80
7860 Lessines
Belgium

Bieffe Medital Sabiñanigo
Ctra de Biescas, Senegüé
22666 Sabiñanigo (Huesca)
Spain

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For information about Potassium 0.15 & Sodium 0.9 Infusion or to request this leaflet in formats such as audio or large print please contact the Marketing Authorisation Holder:
Tel: +44 (0)1635 206345.

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Potassium Chloride 0.15 % w/v & Sodium Chloride 0.9% w/v Solution for Infusion BP

The following information is intended for medical or healthcare professionals only:

Handling and Preparation

Use only if the solution is clear, without visible particles and if the container is undamaged.
Administer immediately following the insertion of infusion set.
Do not remove unit from overwrap until ready for use.
The inner bag maintains the sterility of the product.
Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before the administration of the fluid from the secondary container is completed.
The solution should be administered with sterile equipment using an aseptic technique. The equipment should be primed with the solution in order to prevent air entering the system.
Additives may be introduced before infusion or during infusion through the re-sealable medication port. When additive is used, verify isotonicity prior to parenteral administration. Thorough and careful aseptic mixing of any additive is mandatory.
Solutions containing additives should be used immediately and not stored.
After addition, if there is a colour change and/or the appearance of precipitates, insoluble complexes or crystals, do not use.

Adding medication or using an incorrect administration technique might cause the appearance of fever reactions due to the possible introduction of pyrogens. In case of adverse reaction, infusion must be stopped immediately.

Discard after single use.

Discard any unused portion.

Do not reconnect partially used bags.

1. Opening

a. Remove the Viaflo container from the overpouch just before use.

b. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution, as sterility may be impaired.

c. Check the solution for limpidity and absence of foreign matters. If solution is not clear or contains foreign matters, discard the solution.

2. Preparation for administration

Use sterile material for preparation and administration.

a. Suspend container from eyelet support.

b. Remove plastic protector from outlet port at bottom of container:
   - grip the small wing on the neck of the port with one hand,
   - grip the large wing on the cap with the other hand and twist,
   - the cap will pop off.

c Use an aseptic method to set up the infusion.

d. Attach administration set. Refer to complete directions accompanying set for connection, priming of the set and administration of the solution.

3. Techniques for injection of additive medications

The solution should not be administered in the atrium or ventricle to avoid localised hyperkalaemia, but in large peripheral or central vein to diminish the risk of causing sclerosis.
Warning: Additives may be incompatible (see paragraph 5 "Incompatibilities of additive medications" below).

To add medication before administration

a. Disinfect medication port .

b. Using syringe with 19 gauge (1.10 mm) to 22 gauge (0.70 mm) needle, puncture re-sealable medication port and inject.

c. Mix solution and medication thoroughly. For high-density medication such as potassium chloride, tap the ports gently while ports are upright and mix.

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Caution: Do not store bags containing added medications.

To add medication during administration

a. Close clamp on the set
b. Disinfect medication port .
c. Using syringe with 19 gauge (1.10 mm) to 22 gauge (0.70 mm) needle, puncture re-sealable medication port and inject.
d. Remove container from IV pole and/or turn to an upright position.
e. Evacuate both ports by tapping gently while the container is in an upright position.
f. Mix solution and medication thoroughly.
g. Return container to in use position, re-open the clamp and continue administration

4. In-use shelf life (Additives)

Chemical and physical stability of any additive medication at the pH of the Potassium 0.15& Sodium 0.9 Infusion in the Viaflo container should be established prior to use. From a microbiological point of view, the diluted product must be used immediately unless dilution has taken place in controlled and validated aseptic conditions.

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

5. Incompatibilities of additive medications

As with all parenteral solutions, incompatibility of the additive medications with the solution must be assessed before addition.
In the absence of compatibility studies, this solution must not be mixed with other medicinal products.
It is the responsibility of the physician to judge the incompatibility of an additive medication with the Potassium 0.15 & Sodium 0.9 Infusion, by checking for eventual colour change and/or eventual appearance of precipitate, insoluble complexes or crystals. The Instructions for Use of the medication to be added must be consulted.
Before adding a drug, verify it is soluble and/or stable in water at the pH of the Potassium 0.15 & Sodium 0.9 Infusion (pH: 4.5 to 7.0).
Those additives known to be incompatible should not be used.

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