Baxter

PACKAGE LEAFLET: INFORMATION FOR THE USER

Potassium Chloride 0.15% w/v & Glucose 5% w/v Solution for Infusion BP

Active substances: potassium chloride and glucose monohydrate

Read all of this leaflet carefully before you are 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.

What is in this leaflet:

1. What Potassium 0.15 & Glucose Infusion is and what it is used for

Potassium 0.15 & Glucose Infusion is a solution of potassium chloride and glucose in water. Potassium chloride is a chemical substance (often called a "salt") found in the blood. Glucose is one of the body's sources of energy. This solution for infusion provides 200 kilocalories per litre.

Potassium 0.15 & Glucose Infusion is used as a source of carbohydrate (sugar) in the prevention and treatment of:

- 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 potassium 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 are given Potassium 0.15 & Glucose Infusion

Do NOT receive Potassium 0.15 & Glucose Infusion if you are suffering from any of the following conditions

- higher levels of potassium in the blood than normal (hyperkalaemia)
- higher levels of chloride in the blood than normal (hyperchloraemia)
- 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).
- diabetes that is not adequately treated, allowing your blood sugar levels to rise above normal (uncompensated diabetes)
- states of glucose intolerance, for example:
  - metabolic stress (when the body's metabolism does not function correctly, e.g. due to severe illness)
  - hyperosmolar coma (unconsciousness). This is a type of coma that can occur if you have diabetes and do not receive enough medicine.
  - a higher amount of sugar in the blood than normal (hyperglycaemia)
  - a higher amount of lactate in the blood than normal (hyperlactataemia)
- if you are allergic to potassium chloride and glucose monohydrate or any other ingredients of this medicine (listed in Section 6).

Warning and precautions

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

- heart failure
- respiratory failure (lung disease)
- any type of heart disease or poor heart function
- poor kidney function
  (special monitoring may be required in the above conditions)
- adrenocortical insufficiency (this disease of the 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)
- head injury within the past 24 hours
- a high pressure within the skull (intracranial hypertension)
- if you have recently had a stroke
- allergy to corn (Potassium 0.15 & Glucose Infusion contains sugar derived from corn, see section 4)
- 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 & Glucose Infusion").

  This may increase the risk of low level 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 and monitor:

- the amount of fluid in your body
- the amount of sugar (glucose)
- your vital signs
- the amount of chemicals such as sodium and potassium in your blood (your plasma electrolytes)
- the blood concentration of a substance called creatinine (your plasma creatinine)
- the blood concentration of a substance called urea (your BUN levels)
- 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 & Glucose Infusion you may need to be given extra nutrition

As Potassium 0.15 & Glucose Infusion contains sugar (glucose), it can cause a high level of sugar in the blood (hyperglycaemia). If this occurs, your doctor may:

- adjust the speed of infusion
- give you insulin to reduce the blood sugar levels

This is particularly important if you are diabetic.

Children

Potassium 0.15 & Glucose Infusion should be given with special care in children.
In newborns, especially born premature and with low birth weight are at increased risk of developing a too low or too high level of sugar in the blood (hypo or hyperglycemia) due to infusion of glucose solutions. Low level of sugar in the newborn can cause prolonged seizures, coma and brain damage. High level of sugar has been associated with bleeding into the brain, late onset bacterial and fungal infection, infection in the intestinal track (necrotizing enterocolitis), affects eyes (retinopathy of prematurity), lungs problems (bronchopulmonary dysplasia), prolonged length of hospital stay, and death.
Pediatric patients should be closely monitored. In cases where normal regulation of the water content of the blood is disturbed due to increased secretion of Antidiuretic Hormone (ADH), the infusion of fluids with a low concentration of sodium chloride (hypotonic fluids) may result in a low level of sodium in the blood (hyponatraemia). This can lead to headache, nausea, seizures, lethargy, coma, swelling of the brain (cerebral oedema) and death; therefore these symptoms (acute symptomatic hyponatraemic encephalopathy) are considered a medical emergency.

Other medicines and Potassium 0.15 & Glucose Infusion

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines.

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

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 or 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).

Potassium 0.15 & Glucose Infusion must not be added or given through the same needle with citrate anticoagulated/preserved blood. This can damage the red blood cells or cause them to clump together.

Potassium 0.15 & Glucose Infusion with food and drink

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

Pregnancy, breast-feeding and fertility

Ask your doctor or nurse for advice before taking this medicine.

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

Changes in the potassium levels in your blood can affect how well your heart and your unborn baby's heart work. Your doctor will therefore carefully monitor the levels of the chemicals in your blood.

Potassium 0.15 & Glucose Infusion can be given during pregnancy. The amount you are given must be carefully controlled by your doctor.

However, 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 & Glucose Infusion does not affect your ability to drive or use machines.

3. How you will be given Potassium 0.15 & Glucose Infusion

Potassium 0.15 & Glucose 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, condition, state of hydration (the amount of water in your body) and the reason for treatment. The amount you are given may also be affected by other treatments you are receiving.

You should NOT be given Potassium 0.15 & Glucose 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 & Glucose Infusion, your doctor may monitor your ECG (heart tracing).

Potassium 0.15 & Glucose 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 levels of the hormone vasopressin, or if you are are taking other medicines which increase the effects 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 & Glucose Infusion from a bag that has been partly used.

If you receive more Potassium 0.15 & Glucose Infusion than you should

If you are given too much Potassium 0.15 & Glucose Infusion (over-infusion), or you are given your infusion too quickly, this

may lead to the following symptoms:

- water overload with build up of liquid in the tissues causing swelling
- pins and needles in the arms and legs (paresthesia)
- muscle weakness
- an inability to move (paralysis)
- an irregular heartbeat (cardiac arrhythmias)
- heart block (a very slow heartbeat)
- cardiac arrest (the heart stops beating; a life-threatening situation)
- confusion
- acidification of the blood (acidosis) leading to tiredness, confusion, lethargy and increased breathing rate

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 & Glucose 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.

Stop receiving your Potassium 0.15 & Glucose 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 & Glucose 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)
- hypersensitivity reactions, including a serious allergic reaction called anaphylaxis (potential manifestation in patients with allergy to corn)
- chills

Low levels of sodium in the blood that may be acquired during hospitalization (nosocomial hyponatraemia) and related neurological disorders (acute hyponatremic encephalopathy). Hyponatraemiacan lead to irreversible brain injury and death due to cerebral oedema/swelling (see also in section 2 “warnings and precautions”)

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

Ireland
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

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

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

5. How to store Potassium 0.15 & Glucose Infusion

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

Potassium 0.15 & Glucose Infusion does not require special storage conditions.

Potassium 0.15 & Glucose Infusion should NOT be given to you after the expiry date which is stated on the bag after EXP. The expiry date refers to the last day of that month.

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

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6. Contents of the pack and other information

What Potassium 0.15 & Glucose Infusion contains

The active substances are:

- potassium chloride: 1.5 g per litre
- glucose (as monohydrate): 50 g per litre.

The other ingredients are

- hydrochloric acid, concentrated
- water for injections

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

Potassium 0.15 & Glucose 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 :

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

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 Sabiñánigo
Ctra de Biescas, Senegüé
22666 Sabiñanigo (Huesca)
Spain

Manufacturers for Ireland:

Baxter SA
Boulevard René Branquart, 80
7860 Lessines
Belgium

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

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For information about Potassium 0.15 & Glucose 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 & Glucose 5% w/v Solution for Infusion BP

The following information is intended for 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.
Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.
Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

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 unless dilution has taken place in controlled and validated aseptic conditions.
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.

Paediatric population
In order to avoid potentially fatal over infusion of intravenous fluids to the neonate, special attention needs to be paid to the method of administration. When using a syringe pump to administer intravenous fluids or medicines to neonates, a bag of fluid should not be left connected to the syringe.
When using an infusion pump all clamps on the intravenous administration set must be closed before removing the administration set from the pump, or switching the pump off. This is required regardless of whether the administration set has an anti free flow device.
The intravenous infusion device and administration equipment must be frequently monitored.

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.

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 & Glucose 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 & Glucose 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 & Glucose Infusion (pH: 3.5 to 6.5).

As a guidance the following medications are incompatible with Potassium 0.15 & Glucose Infusion ***(non-exhaustive listing)***:

- amphotericin B
- dobutamine

Glucose should not be administered through the same infusion equipment as whole blood as haemolysis and clumping can occur.

Those additives known to be incompatible should not be used.