Baxter

PACKAGE LEAFLET: INFORMATION FOR THE USER

Potassium Chloride 0.15% w/v, Sodium Chloride 0.18% w/v and Glucose 4% w/v Solution for Infusion

Active substances: potassium chloride, sodium 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.

Throughout this leaflet, Potassium Chloride 0.15% w/v, Sodium Chloride 0.18% w/v and Glucose 4% w/v, Solution for Infusion will be called Potassium chloride, Sodium chloride & Glucose Infusion

What is in this leaflet:

1. What Potassium chloride, Sodium chloride & Glucose Infusion is and what it is used for

Potassium chloride, Sodium chloride & Glucose Infusion is a solution of potassium chloride, sodium chloride and glucose monohydrate in water. Potassium chloride and sodium chloride are chemicals (often called “salts”) found in the blood.

It is used to prevent and treat the following conditions:

- if you do not have enough potassium, sodium and chloride in your blood. This can occur when gastrointestinal (stomach) fluid is lost. This can happen if:
  - you have vomiting
  - you have diarrhoea
  - a wound is drained after surgery (by collecting body fluid in a bag)
  - you have gastric (stomach) suction to empty the stomach contents
  - part of your digestive system has been diverted so that food does not pass through the small bowel. This procedure is called small intestinal bypass
  - you have a hole in the small bowel (small bowel fistula)
- if you take too many laxatives (drugs to empty your bowels)
- if you have a malabsorption syndrome (you cannot absorb enough nutrients)
- if you have a tumour in your small intestine that produces mucus (mucus secreting villous adenoma)
- if you have kidney problems that cause you to lose too much salt
- if you take too many diuretics (water tablets that increase urine production)
- if you cannot eat so that you need more energy

2. What you need to know before you are given Potassium chloride, Sodium chloride & Glucose Infusion

Do NOT receive Potassium chloride, Sodium chloride & 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.
- If you have higher amount of sugar in the blood than normal (hyperglycaemia)
  - a higher amount of lactate in the blood than normal (hyperlactataemia)
- recent stroke
- head injury within the last 24 hours
- if you are allergic to potassium chloride, sodium chloride and glucose monohydrate or any other ingredients of this medicine (listed in Section 6).

Your doctor will take special care when giving you Potassium chloride, Sodium chloride & Glucose Infusion

Potassium chloride, Sodium chloride & Glucose Infusion is a hypertonic (concentrated) solution. Once administered, the solution becomes hypotonic due to its low sodium content.
Your doctor will take this into account when calculating how much to give you.

Warnings and precautions

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

- any condition that causes you to have high blood potassium (hyperkalaemia) such as:
  - poor kidney function
  - adrenocortical insufficiency. This is a disease that affects the hormones that control the concentration of chemicals in the body.
  - acute dehydration (a rapid loss of water from the body, e.g. from vomiting or diarrhoea)
- extensive tissue damage (as can occur in severe burns)
- high blood pressure (hypertension)
- a build up of fluid under the skin (peripheral oedema), particularly around the ankles
- a build up of fluid in the lungs (pulmonary oedema)
- high blood pressure during pregnancy (pre-eclampsia)
- any condition associated with sodium retention (when the body has too much sodium), such as treatment with steroids (drugs that reduce inflammation) (See also below "Other medicines and Potassium chloride, Sodium chloride & Glucose Infusion").
- diabetes, where insulin treatment may need to be changed because of the glucose (a type of sugar) in the solution
- allergy to corn (Potassium chloride, Sodium chloride & Glucose Infusion contains sugar derived from corn)
- 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 chloride, Sodium chloride & 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

If you have any of these conditions, you will need additional tests to monitor your health. Your doctor will take blood and urine samples to monitor the amount of chemicals in your blood (your plasma electrolytes). You will also have a heart tracing (ECG).

You might have changes made to your other medicines.

Children

Potassium chloride, Sodium chloride & Glucose Infusion should be given with special care in children.

Newborns, especially those born premature and with a low birth weight, are at increased risk of developing a too low or too high level of sugar in the blood (hypo or hyperglycaemia) due to infusion of glucose solutions. Low levels 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), eye problems (retinopathy of prematurity), lung problems (bronchopulmonary dysplasia), prolonged length of hospital stay, and death.

Children are at higher risk for having or developing a too low sodium concentration in their blood (hyponatraemia). Hyponatraemia can lead to headache, nausea, seizures, lethargy, coma, swelling of the brain (cerebral oedema) and death. Acute hyponatraemic encephalopathy is a serious complication, especially in children.

Your doctor knows this and will closely monitor the amount of chemicals such as sodium and chloride in your child's blood (plasma electrolytes)

Other medicines and Potassium chloride, Sodium chloride & Glucose Infusion

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

Other medicines that can affect or be affected by Potassium chloride, Sodium chloride & Glucose Infusion include:

- lithium (used to treat psychiatric illnesses)
- potassium-sparing diuretics (some water tablets, e.g. amiloride, spironolactone, triamterene)
- medicines that contain potassium (e.g. potassium supplements, salt substitutes containing potassium and some types of penicillin)
- medications that increase the risk of hyponatremia or sodium and fluid retentionangiotensin converting enzyme (ACE) inhibitors (used to treat high blood pressure)
- cyclosporin (used to prevent rejection of a transplant)
- 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 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).

If you need a blood transfusion at the same time as your infusion, you will be given the blood into another vein.

Potassium chloride, Sodium chloride & 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.

There is a small possibility that if you are given Potassium chloride, Sodium chloride & Glucose Infusion during labour, glucose could affect the unborn baby by causing:

- hyperglycaemia (high blood sugar, which causes severe thirst, dry mouth and frequent urination)
- hyperinsulinaemia (high levels of insulin, the hormone that regulates blood sugar. Blood glucose (sugar) levels can become too low)
- acidosis (an imbalance in blood chemistry) that can lead to low blood sugar and jaundice (yellow colour of the skin or whites of the eyes)

However, the relationship between glucose infusion and these effects has not been proven.

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

The infusion does not affect your ability to drive or use machines.

3. How you will be given Potassium chloride, Sodium chloride & Glucose Infusion

The 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 (your state of health). It will also depend on the other medicines that you take.

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

The 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.

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 are taking other medicines which increase the effects of vasopressin).

If you suffer from poor kidney function, you will receive a lower dose.

If you receive more Potassium chloride, Sodium chloride & Glucose Infusion than you should

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

- high levels of sugar in the blood (hyperglycaemia), which causes severe thirst, dry mouth and frequent urination)
- low levels of sodium in the blood (hyponatraemia). Hyponatraemia can lead to headache, nausea, seizures, lethargy, coma, swelling of the brain (cerebral oedema) and death
- fluid collection under the skin (peripheral oedema), particularly around the ankles
- high levels of potassium (hyperkalaemia), Symptoms includes:
  - pins and needles (paraesthesia) in the arms and legs
  - respiratory paralysis (inability to breathe)
  - gastrointestinal symptoms (painful obstruction of intestine., nausea, vomiting, abdominal pain)
  - hypotension (low blood pressure)
  - muscle weakness
  - an inability to move your muscles (paralysis)
  - irregular heartbeat (cardiac arrhythmia)
  - heart block (a very slow heartbeat)
  - cardiac arrest (the heart stops beating; a life-threatening condition)

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 the Potassium chloride, Sodium chloride & Glucose Infusion and you receive more than you should, the added medicine may also cause side effects. You should read the Package Leaflet of the added medicine for a list of possible symptoms.

Stop receiving your Potassium chloride, Sodium chloride & 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 chloride, Sodium chloride & Glucose Infusion can cause side effects, although not everybody gets them.

The side effects that may occur due to the administration method include:

- hypersensitivity reactions, including a serious allergic reaction called anaphylaxis (potential manifestation in patients with allergy to corn).
- hyponatremia (low level of sodium in body fluids) that may be acquired during hospitalization (nosocomial hyponatraemia) and related neurological disorder (acute hyponatremic encephalopathy). Hyponatraemiacan lead to irreversible brain injury and death due to cerebral oedema/swelling (see also section 2 “warnings and precautions”)
- hyperglycemia (high levels of sugar in the blood)
- irritation and inflammation of the vein into which the solution is infused (phlebitis). This
- can cause redness, pain or burning, and swelling of the vein
- rash
- pruritus (itchy skin)
- fever (pyrexia)
- infection at the site of infusion

- local pain or reaction (redness or swelling) at the site of the infusion
- injection site vesicles
- chills
- high level of potassium in the blood (hyperkalaemia)
- cardiac arrest
- the formation of a clot in the injected vein (venous thrombosis), which causes pain, swelling or redness.
- escape of the infusion solution (extravasation) into the tissues around the vein. This can damage the tissues and cause scarring.
- too much fluid in the blood vessels (hypervolaemia)

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.

If you get any side effects talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet.

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

United Kingdom
Via the Yellow Card Scheme:
website: www.mhra.gov.uk/yellowcard

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.

5. How to store Potassium chloride, Sodium chloride & Glucose Infusion

Potassium chloride, Sodium chloride & Glucose Infusion does not require any special storage conditions.

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

The Potassium chloride, Sodium chloride & 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 chloride, Sodium chloride & Glucose Infusion, if:

- there are particles in the solution
- the solution changes colour, or
- the container is damaged in any way

6. Contents of the pack and other information

This leaflet does not contain all the information about this medicine. If you have any questions or are not sure about anything, ask your healthcare professional.

What Potassium chloride, Sodium chloride & Glucose Infusion contains

The active substances are potassium chloride (1.5 g per litre), sodium chloride (1.8 g per litre) and glucose (40 g per litre, equivalent to 44 g glucose as monohydrate).

The only other ingredient is water for injection

What Potassium chloride, Sodium chloride & Glucose Infusion looks like and contents of the pack

Potassium chloride, Sodium chloride & 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 bag.

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

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

TH-30-02-236

Send all enquires to this address

Potassium chloride, Sodium chloride & Glucose Infusion can be made at any of these addresses:

Manufacturers for Great Britain:

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:

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

This leaflet was last revised in June 2023

For information about Potassium chloride, Sodium chloride & 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.

Baxter and Viaflo are trademarks of Baxter International Inc.

TH-30-02-236

Baxter

Potassium Chloride 0.15% w/v, Sodium Chloride 0.18% w/v and Glucose 4% w/v Solution for Infusion

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 to prevent air entering the system.

Additives may be introduced before or during infusion through the resealable medication port.

Additives known or determined to be incompatible should not be used.

Before adding a substance or medication, verify that it is soluble and/or stable in Potassium Chloride 0.15 % w/v, Sodium Chloride 0.18 % w/v and Glucose 4% w/v Solution for Infusion and that the pH range of Potassium Chloride 0.15 % w/v, Sodium Chloride 0.18 % w/v and Glucose 4% w/v Solution for Infusion is appropriate.

The instructions for use of the medication to be added and other relevant literature must be consulted.

After addition, if there is a colour change and/or the appearance of precipitates, insoluble complexes or crystals, do not use.

Mix the solution thoroughly when additives have been introduced.

Do not store solutions containing additives.

For single use only.

When additive is used, verify tonicity prior to parenteral administration. Thorough and careful aseptic mixing of any additive is mandatory. Solutions containing additives should be used immediately after preparation, unless preparation has taken place in controlled and validated aseptic conditions.

Adding other 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 the inner bag firmly. If leaks are found, discard the solution, as the solution may no longer be sterile.

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

2. Preparation for administration

Use sterile material for preparation and administration.

a. Suspend the container from the eyelet support.
b. Remove the plastic protector from the outlet port at the bottom of the 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 the administration set. Refer to the complete directions accompanying the set for connection, priming of the set and administration of the solution.

3. Techniques for injection of additive medications

Warning: Additives may be incompatible (see paragraph 5 "Incompatibilities of additive medications" below).

To add medicinal product before administration

a. Disinfect medication site.
b. Using syringe with 19 to 22 gauge needle, puncture resealable 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 medicinal product during administration

a. Close clamp on the set.
b. Disinfect medication port.
c. Using syringe with 19 to 22 gauge needle, puncture resealable 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 Potassium chloride, Sodium chloride & 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, before adding medications, compatibility of these additives with the solution in the VIAFLO container must be assessed.

It is the responsibility of the physician to judge the incompatibility of an additive medication with Potassium chloride, Sodium chloride & Glucose Infusion by checking for eventual colour change and/or eventual precipitate, insoluble complexes or the appearance of crystals.

The Instructions for Use of the medication to be added must be consulted.

Before adding a drug, verify that it is soluble and stable in water at the pH of Potassium chloride, Sodium chloride & Glucose Infusion. When a compatible medication is added to this formulation, the solution must be administered immediately, unless dilution has taken place in controlled and validated aseptic conditions.

As a guide, the following medications are incompatible with Potassium chloride ,Sodium chloride & Glucose Infusion, although this list is not exhaustive:

- 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.

Baxter and Viaflo are trademarks of Baxter International Inc.

TH-30-02-236