Baxter

PACKAGE LEAFLET: INFORMATION FOR THE USER

Potassium Chloride 0.15% w/v & Glucose 10% w/v Solution for Infusion

Active substances: potassium chloride, 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 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 & Glucose 10% w/v Solution for Infusion will be called Potassium 0.15 & Glucose 10 Infusion.

What is in this leaflet:

1. What Potassium Chloride 0.15 & Glucose 10 Infusion is and what it is used for

Potassium Chloride 0.15 & Glucose 10 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 400 kilocalories per litre.

Potassium Chloride 0.15& Glucose 10 Infusion is used to:

- provide a source of carbohydrate (sugar) for parenteral nutrition. Parenteral nutrition is used to feed patients who are unable to eat. It is given as an infusion (slow injection) into a vein.
- prevent or treat a low level of sugar in the blood ((hypoglycaemia, that is causing symptoms, but is not life-threatening).
- give you extra fluid if your body does not have enough water (dehydration), and you need extra carbohydrate (sugar).
- prevent or treat a loss of potassium from the body (potassium depletion, e.g. after treatment with certain diuretics [water tablets])
- prevent or treat 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 Chloride 0.15 & Glucose 10 Infusion

You must NOT receive Potassium Chloride 0.15 & Glucose 10 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)
- higher levels of sugar in the blood than normal (hyperglycaemia)
- 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.
  - higher level of lactate in the blood than normal (hyperlactataemia)
- thinning of the blood due to the addition of too much fluid (haemodilution)
- when there is too much fluid in the spaces around the cells of the body (extracellular hyperhydration)
- when there is a larger volume of blood in the blood vessels than there should be (hypervolaemia)
- build up of fluid under the skin, affecting all parts of the body including your brain and lungs (general oedema)
- liver disease that causes fluid to build up within the abdomen (ascitic cirrhosis)
- any condition which affects the way your body controls your sugar level
- You should NOT be given solutions for infusion containing glucose for the first 24 hours after suffering a head injury. This includes Potassium Chloride 0.15 & Glucose 10 Infusion.
- If another medicine is added to your solution for infusion, always read the Patient Information Leaflet of that medicine. This way you can check to see if that medicine is safe for you to take.

Warnings and precautions

Potassium Chloride 0.15 & Glucose 10 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.

- changes in the concentrations of the chemicals in the blood (electrolyte disturbances)
- an excess of fluid in the blood vessels (hypervolaemia)
- build up of fluid under the skin, affecting all parts of the body (general oedema), around the ankles (peripheral oedema) or in the lungs (pulmonary oedema)

The infusion may cause:

- a higher amount of sugar in the blood than normal (hyperglycaemia), especially with states of glucose intolerance, for example:
  - diabetes that is not adequately treated, allowing your blood sugar levels to rise above normal (diabetes mellitus)
  - head injury within the past 24 hour
  - metabolic stress (when the body's metabolism does not function correctly, e.g. due to severe illness)
- a higher amount of potassium in the blood than normal (hyperkalaemia), especially with:
  - burns and injuries
  - heart failure
  - extreme muscle weakness or paralysis
  - muscle weakness for children (paramyotonia congenita)
  - adrenocortical insufficiency. This is a disease that affects the hormones that control the concentration of chemicals in the body
- a disorder in which the blood becomes too alkaline (metabolic alkalosis)
- muscle weakness and periodic paralysis due to low thyroid activity (thyrotoxic periodic paralysis)
- rapid loss of water from the body e.g. due to vomiting or diarrhoea
- being on a low potassium diet for a long time
- aldosteronism (a disease that causes high levels of a hormone called aldosterone)
- allergy, in particular to corn (Potassium 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 0.15 & Glucose 10 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 adjust how much solution for infusion you are given according to the results of these tests.

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 Chloride 0.15 & Glucose 10 Infusion you may need to be given extra nutrition

Potassium Chloride 0.15 & Glucose 10 Infusion must not be given through the same needle as a blood transfusion. This can damage the red blood cells or cause them to clump together.

Other medicines and Potassium Chloride 0.15 & Glucose 10 Infusion

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

Potassium Chloride 0.15 & Glucose 10 Infusion and other medicines taken at the same time can affect each other.

Do not take Potassium Chloride 0.15 & Glucose 10 Infusion with certain hormones (catecholamines) including adrenaline or steroids as they can increase the level of sugar in your blood.

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)
- corticosteroids (anti-inflammatory medicines)
- 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)
- medications that increase the risk of hyponatremia or sodium and fluid retention

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 Chloride 0.15 & Glucose 10 Infusion with food and drink and alcohol

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

Pregnancy and breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist 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 Chloride 0.15 & Glucose 10 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 Patient Information Leaflet of the medicine that is to be added.

Driving and using machines

Potassium Chloride 0.15 & Glucose 10 Infusion does not affect your ability to drive or use machines.

3. How you will be given Potassium 0.15 & Glucose 10 Infusion

Potassium Chloride 0.15 & Glucose 10 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 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 Chloride 0.15 & Glucose 10 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 Chloride 0.15 & Glucose 10 Infusion, your doctor may monitor your ECG (heart tracing).

Potassium Chloride 0.15 & Glucose 10 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 Chloride 0.15 & Glucose 10 Infusion from a bag that has been partly used.

If you receive more Potassium Chloride 0.15 & Glucose 10 Infusion than you should

If you are given too much Potassium Chloride 0.15 & Glucose 10 Infusion (over-infusion), or you are given your infusion too quickly, 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 level of potassium (hyperkalaemia), Symptoms includes:
  - pins and needles in the arms and legs (paresthesia)
  - 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 (paralysis)
  - an irregular heartbeat (cardiac arrhythmias)
  - heart block (a very slow heartbeat)
  - cardiac arrest (the heart stops beating; a life-threatening situation)
- dilution of the blood (haemodilution) and an excess of fluid in the blood vessels (hypervolaemia)
- a higher amount of sugar in the blood than normal (hyperglycaemia)
- the blood becomes too concentrated (hyperosmolarity)
- sugar in the urine (glycosuria)
- an increase in the amount of urine you produce (osmotic diuresis)
- a loss of water from the body (dehydration)
- a fall in the blood levels of phosphate

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 Chloride 0.15 & Glucose 10 Infusion before over-infusion occurs, that medicine may also cause symptoms. You should read the Patient Information Leaflet of the added medicine for a list of possible symptoms.

Stopping your Potassium Chloride 0.15 & Glucose 10 Infusion

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

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

4. Possible Side Effects

Like all medicines, Potassium Chloride 0.15 & Glucose 10 Infusion can cause side effects, although not everybody gets them. If you have any of the following symptoms you should tell your doctor or nurse immediately. These may be signs of a very severe or even fatal allergic (hypersensitivity) reaction:

- swelling of the skin of the face, lips and swelling of the throat
- difficulty breathing
- skin rash
- redness of the skin (erythema)
- hives (urticaria)

You will be given treatment depending on the symptoms

Other side effects are:

- changes in the levels of the chemicals in the blood (electrolyte disturbances), including
  - a high level of potassium in the blood (hyperkalaemia)
  - a low level of magnesium in the blood (hypomagnesaemia)
  - a low level of phosphate in the blood (hypophosphataemia)
- a high level of sugar in the blood (hyperglycaemia).
- sugar in the urine (glycosuria)
- shivering
- sweating

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”)

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

- 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.
  - itchy skin (pruritus)
  - fever (pyrexia)
  - infection at the site of infusion
  - local pain or reaction (redness or swelling at the site of infusion)
  - injection site vesicles
  - feeling of cold (chills)
  - the formation of a blood clot (in the injected vein (venous thrombosis) at the site of infusion,), which causes pain, swelling or redness in the area of the clot
  - escape of the infusion solution (extravasation)

into the tissues around the vein (extravasation).. This can damage the tissues and cause scarring.

- hypersensitivity reactions, including a serious allergic reaction called anaphylaxis (potential manifestation in patients with allergy to corn).
- decrease levels of potassium in the blood (hypokalaemia)
- cardiac arrest
- an excess of fluid in the blood vessels (hypervolaemia)

If you get any side effects talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. If any side effects occur, the infusion must be stopped.

If a medicine has been added to your Potassium Chloride 0.15 & Glucose 10 Infusion before over-infusion occurs, that medicine may also cause symptoms. You should read the Patient Information Leaflet of the added medicine for a list of possible symptoms.

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.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

5. How to store Potassium 0.15 & Glucose 10 Infusion

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

Potassium Chloride 0.15 & Glucose 10 Infusion does not require special storage conditions.

Potassium Chloride 0.15 & Glucose 10 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 Chloride 0.15 & Glucose 10 Infusion, if there are particles floating in the solution or if the unit is damaged in any way.

6. Contents of the pack and other information

What Potassium Chloride 0.15 & Glucose 10 Infusion contains

The active substances are:

- potassium chloride: 1.5 g per litre
- glucose (as monohydrate): 100 g per litre.

The other ingredients are

- hydrochloric acid, concentrated
- water for injections

What Potassium Chloride 0.15 & Glucose 10 Infusion looks like and contents of the pack

Potassium Chloride 0.15 & Glucose 10 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 size is:

- 500 ml

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

- 20 bags or 24 bags of 500 ml

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder:

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

Manufacturers:

Baxter Healthcare Ltd.
Caxton Way, Thetford Norfolk IP24 3SE,
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For information about Potassium Chloride 0.15 & Glucose 10 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 10% w/v Solution for Infusion

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 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.

Before adding a substance or medication, verify that it is soluble and/or stable in Potassium Chloride 0.15 & Glucose 10 Infusion and that the pH range of Potassium Chloride 0.15 & Glucose 10 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.

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 Chloride 0.15 & Glucose 10 solution 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 Chloride 0.15 & Glucose 10 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 Chloride 0.15 & Glucose 10 Infusion (pH: 3.5 to 6.5).

As a guidance the following medications are incompatible with Potassium Chloride 0.15 & Glucose 10 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.

When a compatible medication is added to the Potassium Chloride 0.15 & Glucose 10 Infusion, the solution must be administered immediately

Those additives known to be incompatible should not be used.

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