

PACKAGE LEAFLET: INFORMATION FOR THE USER

Ringer-Acetat Baxter Viaflo Solution for Infusion

Active substances: sodium chloride, potassium chloride, calcium chloride dihydrate, magnesium chloride hexahydrate and sodium acetate trihydrate

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.

This medicine is called 'Ringer-Acetat Baxter Viaflo Solution for Infusion', but will be referred to as 'Ringer-Acetat Baxter Viaflo' throughout the remainder of this leaflet.

What is in this leaflet

1. What Ringer-Acetat Baxter Viaflo is and what it is used for
2. What you need to know before you are given Ringer-Acetat Baxter Viaflo
3. How you will be given Ringer-Acetat Baxter Viaflo
4. Possible side effects
5. How to store Ringer-Acetat Baxter Viaflo
6. Contents of the pack and other information

1. What Ringer Acetate Baxter Viaflo is and what it is used for

Ringer-Acetat Baxter Viaflo is a solution of the following substances in water:

- sodium chloride
- potassium chloride
- calcium chloride dihydrate
- magnesium chloride hexahydrate
- sodium acetate trihydrate.

Sodium, potassium, calcium, magnesium, chloride and acetate are chemical substances found in the blood.

Ringer-Acetat Baxter Viaflo is used:

- to replace body fluid and certain salts (electrolytes) that may have been lost due to illness or injury
- as a short-term treatment for reduced blood volume

2. What you need to know before you are given Ringer Acetate Baxter Viaflo

Do NOT receive Ringer-Acetat Baxter Viaflo if you are suffering from any of the following conditions:

- if you are allergic to sodium chloride, potassium chloride, calcium chloride, magnesium chloride, Sodium acetate or any other ingredients of this medicine listed in section 6.

- Premature neonates and neonates (≤ 28 days of age): Your child must not receive a certain antibiotic called ceftriaxone as a drip into a vein concomitantly with this medicine
- too much fluid around the cells in the body (extracellular hyperhydration)
- greater than normal blood volume (hypervolaemia)

Warnings and precautions

Talk to your doctor or nurse if you have or have had any of the following medical conditions.

- In patients of any age a certain antibiotic named ceftriaxone must not be mixed or given simultaneously with any calcium containing solutions given to you by a drip into your vein. Your doctor knows this and will not give you them together even via different infusion lines or different infusion sites.
- However, in patients older than 28 days your doctor may give calcium and ceftriaxone sequentially one after another if infusion lines at different sites are used or if the infusion lines are replaced or were thoroughly flushed with physiological salt solution between the infusions to avoid precipitation. If you or your child suffer from low blood volume your doctor will avoid to give calcium and ceftriaxone sequentially.
- heart failure (especially if this is being treated with digitalis)
- respiratory failure (lung disease)
- swelling due to build up of fluid in the body (oedema)
- fluid build-up in the belly (abdomen) due to a kind of liver disease (ascitic cirrhosis)
- reduced kidney function (renal insufficiency/impairment)
- high blood pressure (hypertension)
- build up of liquid under the skin, particularly around the ankles (peripheral oedema)
- build up of liquid in the lungs (pulmonary oedema)
- high blood pressure during pregnancy (pre-eclampsia or eclampsia)
- aldosteronism (a disease that causes high levels of a hormone called aldosterone)
- any other condition associated with sodium retention (when the body retains too much sodium), such as treatment with steroids (See also below, “Other medicines and Ringer-Acetate Baxter Viaflo”).
- any condition that means you are more likely to have high blood levels of potassium (hyperkalaemia), such as:
 - kidney failure
 - a disease of the adrenal glands which affects hormones that control the concentration of chemicals in the body (adrenocortical insufficiency)
 - acute dehydration (a loss of water from the body, e.g. due to vomiting or diarrhoea)
 - extensive tissue damage (as can occur in severe burns)(In such cases, close monitoring of your blood potassium level is required)
- any illness causing higher than normal levels of vitamin D, such as sarcoidosis
- myasthenia gravis (a disease that causes progressive muscle weakness)
- recovery after an operation
- If you have problems with the fluid levels in your brain (for example, because of meningitis, bleeding in the skull or a brain injury)
- if you have a condition that could cause high levels of vasopressin, a hormone regulating fluid in your body, such as
 - a sudden and serious illness or injury
 - you have had surgery
 - brain disease

- you are taking certain medicines (please see section Other medicines and Ringer Acetat Baxter Viaflo)

These conditions may increase the risk of low levels of sodium in your blood, which can lead to headache, nausea, seizures, lethargy, coma and swelling of the brain.

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

- the amount of fluid in your body (fluid balance)
- the levels of chemicals such as sodium, potassium, calcium, magnesium and chloride in your blood and urine (your plasma and urine electrolytes)
- your acid-base balance (the acidity of the blood and urine)

This is especially important for children as they have a limited ability to regulate fluids and electrolytes.

If you have any of these problems, you should be monitored carefully if you are to receive an infusion of a large volume of Ringer-Acetate Baxter Viaflo.

Although Ringer-Acetate Baxter Viaflo contains potassium, it does not contain enough to treat very low blood plasma levels (severe potassium deficiency).

Ringer-Acetate Baxter Viaflo contains substances that can make the blood too alkaline (metabolic alkalosis). However, it does not contain enough to treat you if your blood is too acidic (metabolic acidosis).

If repeated treatment is required, your doctor will also give you other types of infusions. These will cover the needs of your body for other chemicals and nutrients (food).

If you feel any changes in your condition or how you feel during or after the infusion, you should immediately tell your doctor or nurse.

Other medicines and Ringer Acetate Baxter Viaflo

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

The use of the following medicines **is not recommended** while you are receiving an infusion of Ringer-Acetate Baxter Viaflo:

- ceftriaxone (an antibiotic), when given intravenously (see Warnings and precautions)
- suxamethonium, vecuronium and tubocurarine (muscle relaxants used during surgery)
- potassium (one of the salts found naturally in the body)

Other medicines that can affect or be affected if used in combination with Ringer-Acetate Baxter Viaflo:

- corticosteroids (anti-inflammatory medicines)
- other steroids such as oestrogen
- certain water tablets (potassium-sparing diuretics)
- ACE-inhibitors (medicines for high blood pressure)
- tacrolimus used to prevent rejection of a transplant and to treat some skin diseases
- cyclosporin (used to prevent rejection of a transplant)

These may lead to increased levels of potassium and/or sodium in your blood.

The effects of a medicine for heart disease (digitalis) may be increased by the calcium in Ringer-Acetate Baxter Viaflo. This can lead to serious changes in your heartbeat.

Some medicines can increase the level of calcium in blood. These medicines may include:

- certain water tablets (thiazide- diuretics)
- Vitamin D

The removal (elimination) of certain medicines from your body may be increased or decreased by Ringer-Acetate Baxter Viaflo, changing their effects. These include:

- quinidine (used to treat irregular heartbeat, arrhythmia)
- salicylates (used to treat inflammation e.g. aspirin)
- lithium (used to treat psychiatric illnesses e.g. bipolar disorder)
- stimulant medicines (sympathomimetics, such as ephedrine and pseudoephedrine, used in cough and cold preparations)

Some medicines can increase the risk of side effects due to low levels of sodium in the blood. These medicines may include:

- some cancer drugs
- selective serotonin reuptake inhibitors, (used to treat depression)
- certain medicines used to treat psychiatric disorders (antipsychotics)
- morphine-like drugs (opioids)
- medicines for pain and/or inflammation [also known as *non steroidal anti-inflammatory drugs* (NSAIDs)]
- certain medicines against epilepsy
- oxytocin (drug used during the treatment of women undergoing pregnancy, childbirth and post pregnancy care)
- diuretics

Ringer-Acetate Baxter Viaflo with food and drink

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

Pregnancy, 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 nurse for advice before taking this medicine.

You can be given Ringer-Acetate Baxter Viaflo while you are pregnant or breast feeding.

Driving and using machines

Ringer-Acetate Baxter Viaflo does not affect your ability to drive or use machines.

3. How to use Ringer-Acetate Baxter Viaflo

Dosage

You will be given Ringer-Acetate Baxter Viaflo by a doctor or nurse. Your doctor will decide how much you need and when it is to be administered. This will depend on your age, weight, condition 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 Ringer-Acetate Baxter Viaflo if there are particles floating in the solution or if the pack is damaged in any way.

Administration

Ringer-Acetat Baxter Viaflo 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.

Any unused solution should be thrown away. You should NOT be given an infusion of Ringer-Acetat Baxter Viaflo from a bag that has been partly used.

If you receive more Ringer-Acetat Baxter Viaflo than you should:

If you should happen to receive too much Ringer-Acetat Baxter Viaflo, the doctor and hospital staff will know what precautions to take.

If you are given too much Ringer-Acetat Baxter Viaflo (over-infusion) or it is given too fast, this may lead to the following symptoms:

- build up of fluid in the tissues (hyperhydration) seen as tightened skin
- pooling of the blood in the legs (venous stasis)
- swelling (oedema) – possibly affecting the lungs, affecting breathing, or the brain, causing headache
- changes in the acidity or salt content of your blood
- increased concentration of salts in your blood (serum hyperosmolarity)

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 Ringer-Acetat Baxter Viaflo 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 Ringer-Acetat Baxter Viaflo

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, this medicine 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 rare but 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)

You will be given treatment depending on the symptoms

The other side effects are listed according to their frequencies.

Common (affects 1 to 10 users in 100)

- heart failure can develop in patients with a pre-existing heart disorder
- build up of fluid in the lungs (pulmonary oedema).

- fever, infection (redness, swelling) local pain, blood clot, inflammation or irritation in the vein around the injection site.
- leakage of infusion fluid into surrounding tissue (extravasation).

Rare (affects 1 to 10 users in 10.000)

- chest tightness or chest pain
- slow heart beat (bradycardia) or fast heart beat (tachycardia).

Very rare (affects less than 1 of 10 000)

- fits (seizures) while the solution is being infused

Not Known (frequency cannot be estimated from the available data)

- hypersensitivity reactions
- local or widespread hives (urticaria), with skin rash and itching.
- too much fluid in the blood vessels (overhydration);
- changes in levels of salt and/or acid/base balance of the blood
- low levels of sodium in the blood (hyponatraemia).
- swelling of the brain, may cause brain injury

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 effect, talk to your doctor or nurse. This includes any possible side effect not listed in this leaflet. You can also report side effects directly via **the national reporting system listed in appendix V**. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Ringer-Acetate Baxter Viaflo

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

This medicinal product does not require any special storage conditions

Do not use this medicine after the expiry date which is stated on the bag. The expiry date refers to the last day of that month.

Do not use this medicine if you notice particles floating in the solution or if the unit is damaged in any way.

6. Contents of the pack and other information

What Ringer-Acetate Baxter Viaflo contains

The active substances are:

- sodium chloride 5,86 g per litre,
- potassium chloride 0,30 g per litre,

- calcium chloride dihydrate 0,29 g per litre,
- magnesium chloride hexahydrate 0,20 g per litre,
- sodium acetate trihydrate 4,08 g per litre.

The other ingredients are:

- water for injections
- hydrochloric acid (for adjustment of pH).

What Ringer-Acetat Baxter Viaflo looks like and contents of the pack

Ringer-Acetat Baxter Viaflo 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 bags of 1000 ml
- 12 bags of 1000 ml

Not all pack sizes may be marketed

Marketing authorisation Holder:

<To be completed nationally>

Manufacturer:

Bieffe Medital S.A.
Ctra de Biescas, Senegüé
22666 Sabiñánigo (Huesca)
Spain

This medicinal product is authorised in the Member States of the EEA under the following names:

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The following information is intended for healthcare professionals only:

As this solution contains calcium, it must not be administered through the same infusion equipment as blood, since this can cause the blood to coagulate.

Handling and Preparation

Use only if solution is clear, without visible particles and if the container is undamaged. Administer immediately following the insertion of the 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.

Adding other medications or using an incorrect administration technique might cause the appearance of fever reactions due to the possible introduction of pyrogens. In case of an 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 broken.
- 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

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 at the pH of Ringer Acetat solution in the Viaflo container should be established prior to use.

From a microbiological point of view, the diluted product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C unless reconstitution has taken place in controlled and validated aseptic conditions.

5. Incompatibilities of additive medications

Incompatibility of the medicinal product to be added with the solution in Viaflo container must be assessed before addition.

Ringer-Acetat Baxter Viaflo should not be mixed with products containing carbonates, sulfates or phosphates.

Calcium salts have been reported to be incompatible with a wide range of drugs. Complexes may form resulting in the formation of a precipitate.

- Concomitant treatment with ceftriaxone and Ringer-Acetat Baxter Viaflo is contraindicated in preterm newborns infants and term newborn infants (≤ 28 days of age), even if separate infusion lines are used
- In patients of any age ceftriaxone must not be mixed or administered simultaneously with any calcium-containing IV solutions even via different infusion lines or different infusion sites
- If the same infusion line is used for sequential administration, the line must be thoroughly flushed between infusions with a compatible fluid.

The instruction for use of the medicinal product to be added must be consulted. Before adding a drug, verify it is soluble and stable in water at the pH of Ringer-Acetat Baxter Viaflo (pH 5.0 to 6.0).

As a guidance, the following medications are incompatible with the Ringer-Acetat Baxter Viaflo (non-exhaustive listing):

- Amphotericin B
- Cortisone
- Erythromycin lactobionate
- Etamivan
- Ethyl alcohol
- Thiopental sodium
- Disodium edetate