**PACKAGE LEAFLET: INFORMATION FOR THE USER**

**Compound Sodium Lactate Solution for Infusion BP**

Active substances: sodium chloride, potassium chloride, calcium chloride dihydrate and sodium lactate

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**


This medicine is called "Compound Sodium Lactate Solution for Infusion BP", but will be referred to as "Compound Sodium Lactate Infusion" throughout the document.

## 1. WHAT COMPOUND SODIUM LACTATE INFUSION IS AND WHAT IT IS USED FOR

Compound Sodium Lactate Infusion is a solution of the following substances in water:
- sodium chloride
- potassium chloride
- calcium chloride dihydrate
- sodium lactate.

Sodium, potassium, calcium, chloride and lactate are chemical substances (electrolytes) found in the blood.

Compound Sodium Lactate Infusion is used:
- to treat a loss of body water and chemicals (e.g. by heavy sweating, kidney disorders)
- to treat you, if the volume of blood in your blood vessels is low (hypovolaemia) or if you have low blood pressure (hypotension)
- in metabolic acidosis (when the blood becomes too acidic).

## 2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN COMPOUND SODIUM LACTATE INFUSION

**You must NOT receive Compound Sodium Lactate Infusion if you are suffering from any of the following conditions**
- if you're a newborn (less than 28 days old) receiving ceftriaxone (an antibiotic)
- if you're allergic to sodium lactate or any of the other ingredients in Compound Sodium Lactate (listed in section 6)
- 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)
- 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
- higher levels of potassium in the blood than normal (hyperkalaemia)
- higher levels of calcium in the blood than normal (hypercalcaemia)
- a disorder in which the blood becomes too alkaline (metabolic alkalosis)

- liver disease that causes fluid to build up within the abdomen (ascitic cirrhosis)
- your blood is too acidic which is life-threatening (severe metabolic acidosis)
- a particular type of metabolic acidosis (lactic acidosis)
- severe liver disease (when the liver does not function properly and requires very intensive treatment)
- poor lactate metabolism (this occurs in severe liver disease, as lactate is removed by the liver)
- if you are taking cardiac glycosides (cardiotonics) used to treat heart failure, such as digitalis or digoxin (see also "Taking other medicines").

**Warning and precautions**
Talk to your doctor or nurse before receiving Compound Sodium Lactate Infusion if you have or have had any of the following medical conditions:
- if you're receiving ceftriaxone (an antibiotic) (see also "Other medicines and Compound Sodium Lactate Infusion")
- heart failure
- respiratory failure (lung disease) (special monitoring may be required in the above conditions)
- poor kidney function
- higher levels of chloride in the blood than normal (hyperchloraemia)
- high blood pressure (hypertension)
- build up of fluid under the skin, affecting all parts of the body (general oedema)
- build up of fluid under the skin, particularly around the ankles (peripheral oedema)
- build up of fluid in the lungs (pulmonary oedema)
- high blood pressure during pregnancy (pre-eclampsia)
- a disease that causes high levels of a hormone called aldosterone (aldosteronism)
- higher levels of sodium in the blood than normal (hypernatraemia) or any other condition associated with sodium retention (when the body retains too much sodium), such as treatment with steroids (See also below, "Taking other medicines")
- heart disease of any type
- any condition that means that you are more likely to have high blood levels of potassium (hyperkalaemia), such as:
    - kidney failure
    - adrenocortical insufficiency (this disease of the adrenal gland affects hormones that control the concentration of chemicals in the body)
    - 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)

  Close monitoring of your blood potassium levels is required.
- diseases associated with high levels of vitamin D (e.g. sarcoidosis, a disease affecting the skin and internal organs)
- kidney stones
- poor liver function
- diabetes 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 'Compound Sodium Lactate Infusion').

  This may increase the risk of low levels of sodium in your blood and can lead to headache, nausea, seizures, lethargy, coma, swelling of the brain and death. Brain swelling increases the risk of death and brain damage. People who are at higher risk of brain swelling are:
    - children
    - women (particularly if you are of a fertile age)
    - people who have problems with their brain fluid levels, for example, because of meningitis, bleeding in the skull or a brain injury.

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

- the amount of fluid in your body
- the amount of chemicals such as sodium and potassium in your blood (your plasma electrolytesthe acidity of your blood and urine (your acid-base balance).

Although Compound Sodium Lactate Infusion contains potassium, it does not contain enough to treat very low blood plasma levels of potassium (severe potassium deficiency).

Calcium chloride can be harmful if injected into the body tissues. Therefore, the Compound Sodium Lactate Infusion must not be given by injecting it into a muscle (intramuscular injection). Also, your doctor will make every effort to avoid the escape of the solution into the tissues surrounding the vein.

Compound Sodium Lactate 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.

As Compound Sodium Lactate Infusion contains lactate (a substance found in the body), it can make your blood too alkaline (metabolic alkalosis).

Compound Sodium Lactate Infusion should be given with special care to babies less than 6 months of age. Your doctor will take into account if you are receiving parenteral nutrition (nutrition given by infusion into a vein). If you are given Compound Sodium Lactate Infusion for a long time, you will be given an extra source of nutrients.

**Other medicines and Compound Sodium Lactate 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:
- ceftriaxone (an antibiotic), this should not be given through the same infusion line, unless thoroughly flushed.
- cardiac glycosides (cardiotonics) such as digitalis or digoxin used to treat heart failure, must not be used with Compound Sodium Lactate Infusion (see also section "You must NOT receive Compound Sodium Lactate Infusion if you are suffering from…"). The effects of these drugs can be increased by calcium. This can lead to life threatening changes to the heart rhythm
- corticosteroids (anti-inflammatory medicines)
  These medicines can cause the body to accumulate sodium and water, leading to:
  - tissue swelling due to fluid collection under the skin (oedema)
  - high blood pressure (hypertension).

The following medicines can increase the concentration of potassium in the blood. This effect can be life-threatening. A rise in the blood potassium levels is more likely to occur if you have kidney disease.
- potassium-sparing diuretics (certain water tablets, e.g. amiloride, spironolactone, triamterene) (Note that these medicines may be included in combination medicinal products)
- angiotensin converting enzyme (ACE) inhibitors (used to treat high blood pressure)
- angiotensin II receptor antagonists (used to treat 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).

Some medicines act on the hormone vasopressin. These may include:
- anti-diabetic medication (chlorpropamide)
- cholesterol medicine (clofibrate)
- some cancer drugs (vincristine, ifosfamide, cyclophosphamide)
- selective serotonin reuptake inhibitors (used to treat depression)
- antipsychotics
- opioids for severe pain relief
- medicines for pain and/or inflammation (also known as NSAIDs)
- medicines that imitate or strengthen the effects of vasopressin such as desmopressin (used to treat increased thirst and urination), terlipressin (used to treat bleeding of the gullet) and oxytocin (used to induce labour)

- anti-epileptic medication (carbamazepine and oxcarbazepine)
- diuretics (water tablets).

Other medicines that can affect or be affected by Compound Sodium Lactate Infusion include:
- thiazide diuretics such as hydrochlorothiazide or chlortalidone
- vitamin D
- bisphosphonates (to treat bone diseases such as osteoporosis)
- fluoride (for the teeth and bones)
- fluoroquinolones (a type of antibiotic, including ciprofloxacin, norfloxacin, ofloxacin)
- tetracyclines (a type of antibiotic, including tetracycline)
- acidic medicines, including:
  - salicylates used to treat inflammation (aspirin)
  - barbiturates (sleeping tablets)
  - lithium (used to treat psychiatric illness)
- alkaline (basic) medicines including:
  - sympathomimetics (stimulant medicines such as ephedrine and pseudoephedrine, used in cough and cold preparations)
  - other stimulants (e.g. dexamphetamine, phenfluramine).

**Compound Sodium Lactate Infusion 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 of 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. Compound Sodium Lactate Infusion can be used safely during pregnancy or breast-feeding. Your doctor will monitor the levels of chemicals in your blood and the amount of fluid in your body.

Calcium can reach your unborn baby through the placenta and, after birth, through the breast milk. 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**
Ask your doctor or pharmacist for advice before driving or using machines.

## 3. HOW YOU WILL BE GIVEN COMPOUND SODIUM LACTATE INFUSION

You will be given Compound Sodium Lactate Infusion 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 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 Compound Sodium Lactate Infusion if there are particles floating in the solution or if the pack is damaged in any way.**

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

Any unused solution should be thrown away. You should NOT be given an infusion of Compound Sodium Lactate Infusion from a bag that has been partly used.

**If you receive more Compound Sodium Lactate Infusion than you should**

If you are given too much Compound Sodium Lactate Infusion (over-infusion) or it is given too fast, this may lead to the following symptoms:

- water and/or sodium (salt) overload with build up of liquid in the tissues (oedema) causing swelling
- hyperkalaemia (higher levels of potassium in the blood than normal) especially in patients with kidney failure, causing symptoms such as:
  - pins and needles in the arms and legs (paraesthesia)
  - 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
  - hypercalcaemia (higher levels of calcium in the blood than normal) causing symptoms such as:
    - a decreased appetite (anorexia)
    - feeling sick (nausea)
    - vomiting
    - constipation
    - abdominal pain
    - mental disturbances such as irritability or depression
    - drinking lots of water (polydipsia)
    - producing more urine than normal (polyuria)
    - kidney disease due to build up of calcium in the kidneys (nephrocalcinosis)
    - kidney stones
    - coma (unconsciousness)
    - chalky taste
    - redness (hot flushes)
    - dilatation of the blood vessels in the skin (peripheral vasodilatation).
- Hypokalaemia (lower levels of potassium in the blood than normal) and metabolic alkalosis (when the blood becomes too basic), especially in patients with kidney failure, causing symptoms such as:
  - mood changes
  - tiredness
  - shortness of breath
  - stiffness of the muscles
  - twitching of the muscles
  - contraction of muscles.

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 Compound Sodium Lactate 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.

**Stopping your Compound Sodium Lactate 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 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 very severe or even fatal hypersensitivity (allergic) reaction called anaphylactic shock:

- hives (urticaria) which may be localised to a part of the body or widespread
- skin rash
- redness of the skin (erythema)
- itching (pruritus)
- skin swelling (angioedema)
- coughing
- narrowing of the airways causing difficulty breathing (bronchospasm)
- a fast heartbeat (tachycardia)
- a slow heartbeat (bradycardia)
- decreased blood pressure
- chest discomfort or pain
- anxiety
- tightness of the chest (making it difficult to breathe)
- shortness of breath (dyspnea)
- flushing
- throat irritation
- pins and needles (paraesthesia)
- reduced sense in the mouth (hypoesthesia oral)
- altered taste (dysgeusia)
- fever (pyrexia)
- nausea
- headache.

Higher levels of potassium in the blood than normal (hyperkalaemia)
Low levels of sodium in the blood that may be acquired during hospitalization (nosocomial hyponatraemia) and related neurological disorder (acute hyponatraemic encephalopathy). Hyponatraemia can lead to irreversible brain injury and death due to cerebral oedema/swelling (see also in the section 2"Warning and precautions").

Reactions due to the administration technique manifested by one or more of the following symptoms:

- 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.
- rash or itching (pruritus) of the infusion site.

Other side effects noted with similar products (other sodium-lactate containing solutions) include:

- other manifestations of hypersensitivity/infusion reactions: a blocked nose (nasal congestion), sneezing, swelling in the throat making it difficult to breathe (laryngeal oedema also called Quincke's oedema), skin swelling (angioedema)
- changes in the concentrations of the chemicals in the blood (electrolyte disturbances)
- a larger volume of blood in the blood vessels than there should be (hypervolemia)
- panic attack
- other reactions due to the administration technique: infection at the site of infusion, escape of the infusion solution into the tissues around the vein (extravasation). This can damage the tissues and cause scarring, numbness at the site of infusion.

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.

**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 methods 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
Email: medsafety@hpra.ie.

UK: You can also report side effects directly via the
Yellow Card Scheme at www.mhra.gov.uk/yellowcard

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

## 5. HOW TO STORE COMPOUND SODIUM LACTATE INFUSION

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

250 ml bags: Do not store above 30 °C.
500 ml and 1000 ml bags do not require special storage conditions.

Compound Sodium Lactate Infusion should NOT be given to you after the expiry date which is stated on the bag after EXP: MM/YYYY. The expiry date refers to the last day of that month.

You should not be given Compound Sodium Lactate 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 Compound Sodium Lactate Infusion contains**
The active substances are:
- sodium chloride: 6.00 g per litre
- potassium chloride: 0.40 g per litre
- calcium chloride dihydrate: 0.27 g per litre
- sodium lactate: 3.20 g per litre.

The only other ingredient is water for injections.

**What Compound Sodium Lactate Infusion looks like and contents of the pack**
Compound Sodium Lactate 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:
- 250 ml
- 500 ml
- 1000 ml

Pack sizes:
- 30 bags of 250 ml per carton
- 1 bag of 250 ml
- 20 bags of 500 ml per carton
- 1 bag of 500 ml
- 10 bags of 1000 ml per carton
- 12 bags of 1000 ml per carton
- 1 bag 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
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Netherlands

*Manufacturers:*
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Boulevard René Branquart, 80
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**For Information about Compound Sodium Lactate 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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**The following information is intended for healthcare professionals only:**

**Handling and Preparation**

*Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Do not administer unless the solution is clear and the seal is intact.* Do not remove unit from overwrap until ready for use. The inner bag maintains the sterility of the product. Administer immediately following the insertion of infusion set.

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 is for intravenous administration through a sterile administration set using 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 injection site.
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 medication or using an incorrect administration technique might cause the appearance of fever reactions due to the possible introduction of pyrogens. In case of adverse reaction, infusion must be stopped immediately.

Discard after single use.
Discard any unused portion.
Do not reconnect partially used bags.

**Opening**

- Remove the Viaflo container from the overpouch just before use.
- Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution, as sterility may be impaired.
- Check the solution for clarity and absence of foreign matters. If solution is not clear or contains foreign matters, discard the solution.

**Preparation for administration**

Use sterile material for preparation and administration.

- Suspend container from eyelet support.
- 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.
- Use an aseptic method to set up the infusion.
- Attach administration set. Refer to complete directions accompanying set for connection, priming of the set and administration of the solution.

**Techniques for injection of additive medications**

Warning: Additives may be incompatible Check additive compatibility with both the solution and container prior to use. When additive is used, verify isotonicity prior to parenteral administration. (See Paragraph 5 “Incompatibilities of additive medications” below).

*To add medication before administration*

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

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

## 4. In-use shelf-life: Additives

The chemical and physical stability of any additive at the pH of Compound Sodium Lactate 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

Ceftriaxone must not be mixed with calcium-containing solutions including Compound Sodium Lactate Infusion.

As with all parenteral solutions additives may be incompatible. Compatibility of the additives with the Compound Sodium Lactate Infusion must be assessed before addition. After addition of the additive, incompatibility may become visible by a possible colour change and/or the appearance of precipitates, insoluble complexes or crystals.

The Instructions for Use of the medication to be added and other relevant literature must be consulted.

Before adding a substance or medication, verify it is soluble and/or stable in water at the pH range of Compound Sodium Lactate Infusion (pH 5.0 to 7.0).

When making additions to Compound Sodium Lactate Infusion aseptic technique must be used. Mix the solution thoroughly when additives have been introduced. Do not store solutions containing additives. As guidance the following medications are incompatible with the Compound Sodium Lactate Infusion (***non-exhaustive listing***):

- Medications incompatible with Compound Sodium Lactate Infusion
  - Aminocaproic acid
  - Amphotericin B
  - Metaraminol tartrate
  - Cefamandole
  - CeftriaxoneCortisone acetate
  - Diethylstilbestrol

- Etamivan
- Ethyl alcohol
- Phosphate and carbonate solutions
- Oxytetracycline
- Thiopental sodium
- Versenate disodium

- Medications with partial incompatibility with Compound Sodium Lactate Solution:
  - Tetracycline stable for 12 hours
  - Ampicillin sodium
    concentration of 2%-3% stable for 4 hours
    concentration >3% must be given within 1 hour
  - Minocycline stable for 12 hours
  - Doxycycline stable for 6 hours

Those additives known to be incompatible should not be used.