

## Package leaflet: Information for the user

### Plasma-Lyte® 148 (pH 7.4) Solution for Infusion

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

**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.

This medicine is called 'Plasma-Lyte® 148 (pH 7.4) Solution for Infusion', but will be referred to as 'Plasma-Lyte® 148 (pH 7.4) infusion' throughout the remainder of this leaflet.

#### What is in this leaflet:

1. What Plasma-Lyte® 148 (pH 7.4) Infusion is and what it is used for
2. What you need to know before you use Plasma-Lyte® 148 (pH 7.4) Infusion
3. How to use Plasma-Lyte® 148 (pH 7.4) Infusion
4. Possible side effects
5. How to store Plasma-Lyte® 148 (pH 7.4) Infusion
6. Contents of the pack and other information

#### What Plasma-Lyte® 148 (pH 7.4) Infusion is and what it is used for

Pharmacotherapeutic group: "Electrolytes" - ATC code: "B05BB01"

Plasma-Lyte® 148 (pH 7.4) Infusion is a solution of the following substances in water:

- sodium chloride
- potassium chloride
- magnesium chloride hexahydrate
- sodium acetate trihydrate
- sodium gluconate

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

Plasma-Lyte® 148 (pH 7.4) infusion is used:

- to provide a source of fluid, for example in cases of:
  - burns
  - head injury
  - fractures
  - infection
  - peritoneal irritation (inflammations within the abdomen)
- as a source of fluids during a surgical operation
- for the treatment of shock due to loss of blood and for other conditions needing rapid replacement of blood and/or fluids
- in metabolic acidosis (when the blood becomes too acid) that is not life-threatening
- lactic acidosis (a type of metabolic acidosis caused by the accumulation of lactic acid in the body). Lactic acid is produced mainly by the muscles and is removed by the liver.

Plasma-Lyte® 148 (pH 7.4) infusion can be used:

- in adults, elderly and adolescents
- in infants and toddlers from 28 days to 23 months and children from 2 to 11 years.

## 2. What you need to know before you use Plasma-Lyte® 148 (pH 7.4) Infusion

**You must NOT receive Plasma-Lyte® 148 (pH 7.4) Infusion if you are suffering from any of the following conditions**

- higher levels of potassium in the blood than normal (hyperkalaemia)
- kidney failure
- heart block (a very slow heart beat)
- disorders in which the blood becomes too alkaline (metabolic or respiratory alkalosis)
- a deficiency of acid secretion in the stomach (hypochlorhydria)
- hypersensitivity to the active substances or to any of the ingredients listed in section 6

### Warnings and precautions

Talk to your doctor or nurse before receiving Plasma-Lyte® 148 (pH 7.4) infusion if you have or have had any of the following medical conditions:

- heart failure
- respiratory failure (lung disease)
- kidney failure  
(special monitoring may be required in the above conditions).
- high blood pressure (hypertension)
- 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 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”)
- 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 ‘Plasma-Lyte® 148 (pH 7.4) 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
  - higher levels of chloride in the blood than normal (hyperchloraemia)
  - higher levels of sodium in the blood than normal (hypernatraemia)
  - lower levels of calcium in the blood than normal (hypocalcaemia)
  - any condition that means 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)
- (In such cases, close monitoring of your blood potassium level is required)
- myasthenia gravis (a disease that causes progressive muscle weakness)
  - recovery after an operation

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 and urine (your plasma and urine electrolytes)
- your acid-base balance (the acidity of the blood and urine).

Although Plasma-Lyte® 148 (pH 7.4) Infusion contains potassium, it does not contain enough to treat severe potassium deficiency (very low blood plasma levels).

Plasma-Lyte® 148 (pH 7.4) Infusion contains substances that can cause metabolic alkalosis (making the blood too alkaline).

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 your blood is tested for the presence of a fungus called *Aspergillus*, the test may detect the presence of *Aspergillus* even if it is not present.

### **Other medicines and Plasma-Lyte® 148 (pH 7.4) Infusion**

Tell your doctor or pharmacist 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 Plasma-Lyte® 148 (pH 7.4) Infusion:

- potassium-sparing diuretics (certain water tablets, e.g. amiloride, spironolactone, triamterene, potassium canrenoate)
- 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)

These medicines can increase the concentration of potassium in your blood. This can be life-threatening. A rise in your blood potassium levels is more likely to occur if you have kidney disease.

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 Plasma-Lyte® 148 (pH 7.4) Infusion:

- corticosteroids (anti-inflammatory medicines)
- carbenoxolone (an anti-inflammatory medicine used to treat stomach ulcers)
- neuromuscular blocking agents (e.g. tubocurarine, suxamethonium and vecuronium). These are medicines used in surgical operations and are controlled by your anaesthetist.
- acetylcholine
- aminoglycosides (a type of antibiotic)
- nifedipine (used to treat high blood pressure and chest pain)

- acidic medicines including:
  - salicylates used to treat inflammation (aspirin)
  - sleeping tablets (barbiturates)
  - lithium (used to treat psychiatric illnesses)
- alkaline (basic) medicines including:
  - sympathomimetics (stimulant medicines such as ephedrine and pseudoephedrine, used in cough and cold preparations)
  - other stimulants (e.g. dexamphetamine, phenfluramine)

### **Plasma-Lyte® 148 (pH 7.4) 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 or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

You may receive Plasma-Lyte® 148 (pH 7.4) Infusion if you are pregnant or breast-feeding. Your doctor will monitor the levels of chemicals in your blood and the amount of fluid in your body.

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 to use Plasma-Lyte® 148 (pH 7.4) Infusion**

You will be given Plasma-Lyte® 148 (pH 7.4) Infusion 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 Plasma-Lyte® 148 (pH 7.4) Infusion if there are particles floating in the solution or if the pack is damaged in any way.**

Plasma-Lyte® 148 (pH 7.4) 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 the 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 Plasma-Lyte® 148 (pH 7.4) Infusion from a bag that has been partly used.

### **If you receive more Plasma-Lyte® 148 (pH 7.4) Infusion than you should**

If you are given too much Plasma-Lyte® 148 (pH 7.4) 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
- pins and needles in the arms and legs (paresthesia)
- muscle weakness
- an inability to move (paralysis)

- an irregular heartbeat (cardiac arrhythmias)
- heart block (a very slow heartbeat)
- cardiac arrest (the heart stops beating; a life threatening situation)
- confusion
- loss of the tendon reflexes
- reduced breathing (respiratory depression)
- feeling sick (nausea)
- vomiting
- flushing (redness) of the skin
- thirst
- low blood pressure (hypotension)
- drowsiness
- a slow heartbeat (bradycardia)
- coma (unconsciousness)
- acidification of the blood (acidosis), leading to tiredness, confusion, lethargy and increased breathing rate
- Hypokalaemia (lower levels of potassium in the blood than normal) and metabolic alkalosis (when the blood becomes too alkaline) especially in patients with kidney failure
- mood change
- tiredness
- shortness of breath
- stiffness of muscles
- twitching of the muscles
- contractions 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 Plasma-Lyte<sup>®</sup> 148 (pH 7.4) 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 Plasma-Lyte<sup>®</sup> 148 (pH 7.4) 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, 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 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:

- reactions due to the administration technique:
  - fever (febrile response)
  - infection at the site of infusion
  - burning sensation
  - local pain or reaction (redness or swelling) at the site of infusion

- irritation and inflammation of the vein into which the solution is infused (phlebitis). This can cause redness, pain or burning and swelling along the path of the vein into which the solution is infused.
- the formation of a blood clot (venous thrombosis) at the site of infusion, which causes pain, swelling or redness in the area of the clot
- escape of the infusion solution into the tissues around the vein (extravasation). This can damage the tissues and cause scarring.
- an excess of fluid in the body (hypervolaemia).
- fits (seizures)
- hives (urticaria)
- serious allergic reaction which causes difficulty in breathing or dizziness (anaphylactoid reaction)
- a fast heartbeat (tachycardia)
- palpitations
- chest pain
- chest discomfort
- shortness of breath (dyspnea)
- respiratory rate increased
- flushing
- hyperaemia
- feeling of weakness (asthenia)
- feeling abnormal
- piloerection
- oedema peripheral
- fever (pyrexia)
- 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”).

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.

Other side effects noted with similar products

- Other manifestations of hypersensitivity/infusion reactions: low blood pressure (hypotension), Wheezing, Cold sweat, Chills
- Hyperkalaemia.

### **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 system 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 at:  
[www.mhra.gov.uk/yellowcard](http://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](http://www.hpra.ie);  
 E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

Malta

Website: [www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal)

## **5. How to store Plasma-Lyte® 148 (pH 7.4) Infusion**

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

This medicinal product does not require any special temperature 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 Plasma-Lyte® 148 (pH 7.4) Infusion contains**

The active substances are:

- sodium chloride: 5.26 g per litre
- potassium chloride: 0.37 g per litre
- magnesium chloride hexahydrate: 0.30 g per litre
- sodium acetate trihydrate: 3.68 g per litre
- sodium gluconate: 5.02 g per litre.

The other ingredients are:

- water for injections
- sodium hydroxide.

### **What Plasma-Lyte® 148 (pH 7.4) Solution for Infusion looks like and contents of the pack**

Plasma-Lyte® 148 (pH 7.4) Solution for Infusion is a clear solution, free from visible particles. It is supplied in polyolefin/polyamide plastic bags (Viaflo). Each bag is wrapped in a sealed, protective, outer plastic overpouch.

The bag sizes are:

- 500 ml
- 1000 ml

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

- 1 bag of 500 ml
- 20 bags of 500 ml
- 1 bag of 1000 ml
- 10 bags of 1000 ml
- 12 bags of 1000 ml

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturers**

Marketing Authorisation Holder:

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

Ireland and Malta

**Baxter Holding B.V.**

Kobaltweg 49,  
3542CE Utrecht,  
Netherlands

## Manufacturers:

Baxter SA  
Boulevard René Branquart, 80  
7860 Lessines  
Belgium

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

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

***This medicine is authorised in the Member States of the European Economic Area, and in the United Kingdom (Northern Ireland), under the following names:***

Austria:	Plasmalyt-Infusionslösung
Belgium, Luxemburg:	Plasmalyte A Viaflo, solution pour perfusion
Croatia	Plasma-Lyte 148 (pH 7,4) Viaflo, otopina za infuziju
Czech Republic:	Plasmalyte roztok
Cyprus	Plasma-Lyte 148 (pH 7,4) Solution for infusion
Spain:	Viaflo Plasmalyte 148 (pH 7,4), solución para perfusion
Denmark	Plasmalyte, infusionsvæske, opløsning
Finland	Plasmalyte infuusioneste, liuos
France :	Plasmalyte Viaflo, solution pour perfusion
Greece	Plasma-Lyte 148 (pH 7,4) Solution for infusion
Iceland	Plasmalyte innrennslislyf, lausn
Ireland	Plasma-Lyte 148 (pH 7.4) Solution for infusion
Italy	CrystalSol Solution for infusion
Lithuania	Plasmalyte infuzinis tirpalas
Malta	Plasma-Lyte 148 (pH 7.4) Solution for infusion
Netherlands	Plasma-Lyte 148, oplossing voor infusie
Norway	Plasmalyte infusjonsvæske, oppløsning
Poland	Plasmalyte roztwór do infuzji
Portugal:	Plasma-Lyte (ph 7,4) 148 Viaflo
Slovenia:	Plaslyte raztopina za infundiranje
Slovakia	Plasmalyte infúzny roztok
Sweden	Plasmalyte infusionsvätska, lösning
United Kingdom (Northern Ireland)	Plasma-Lyte 148(pH 7.4) Solution for Infusion

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For information about Plasma-Lyte 148 (pH 7.4) 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**

This solution 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 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 re-sealable medication port. 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 clarity 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* Check additive compatibility with both the solution and container prior to use. 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. (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. **Shelf life after first opening:** The product should be used immediately after opening.

**In-use shelf-life after reconstitution with additives:**

Chemical and physical stability of any additive at the pH of Plasmyte 148 (pH 7.4) 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**

When introducing additives to Plasma-Lyte 148 (pH 7.4), aseptic technique must be used. Mix the solution thoroughly when additives have been introduced. Do not store solutions containing additives.

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

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

Before adding a substance or medication, verify it is soluble and/or stable in water and that the pH range of Plasma-Lyte 148 (pH 7.4) is appropriate (pH 6.5 - 8.0). After addition, check for a possible colour change and/or the appearance of precipitates, insoluble complexes or crystals.

Those additives known to be incompatible should not be used.