Package leaflet: Information for the user

Plasma-Lyte 148 & Glucose 5% w/v Solution for Infusion

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

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. See section 4.

This medicine is called `Plasma-Lyte 148 & Glucose 5% w/v Solution for Infusion', but will be referred to as `Plasma-Lyte & Glucose Infusion' throughout the remainder of this leaflet.

What is in this leaflet:

1. What Plasma-Lyte & Glucose Infusion is and what it is used for

Pharmacotherapeutic group: "Electrolytes with Carbohydrates" - ATC code: "B05BB02"

Plasma-Lyte & Glucose Infusion is a solution of the following substances in water:
- sugar (glucose)
- sodium chloride
- potassium chloride
- magnesium chloride hexahydrate
- sodium acetate trihydrate
- sodium gluconate

Glucose is one of the body's sources of energy. This solution for infusion provides 220 kilocalories per litre. Sodium, potassium, magnesium, chloride, acetate and gluconate are chemical substances found in the blood.

Plasma-Lyte & Glucose infusion is used:
- to provide a source of fluid and carbohydrate (sugar) for example, in cases of:
  - burns
  - head injury
  - fractures
  - infection
  - peritoneal irritation (inflammation within the abdomen)
- as a source of fluids during a surgical operation
- in metabolic acidosis (when the blood becomes too acidic) 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 & Glucose 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 are given Plasma-Lyte & Glucose Infusion

Do NOT receive Plasma-Lyte & Glucose Infusion if you are suffering from any of the following conditions
- higher levels of chloride in the blood than normal (hyperchloraemia)
- higher levels of sodium in the blood than normal (hypernatraemia)
- 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)
- lower levels of calcium in the blood than normal (hypocalcaemia)
- a deficiency of acid secretion in the stomach (hypochlorhydria)
- if you are taking potassium-sparing diuretics (water tablets that cause an accumulation of potassium in the body). Examples are:
  - amiloride
  - potassium canrenoate
  - spironolactone
  - triamterene

  (These medicines may be included in combination medicinal products)
- 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.
  - a higher amount of sugar in the blood than normal (hyperglycaemia)
  - a higher amount of lactate in the blood than normal (hyperlactataemia)
  - hypersensitivity to the active substances or to any of the ingredients listed in section 6.

Warnings and precautions
Plasma-Lyte & Glucose Infusion is a hyper-osmotic (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:
- 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").
- diabetes (your blood sugar levels will be monitored closely and your insulin treatment may need to be modified)
- 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
- head injury within the past 24 hours

- a high pressure within the skull (intracranial hypertension)
- a stroke due to a clot in a blood vessel in the brain (ischaemic stroke)
- 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

  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
- the amount of chemicals such as sodium and potassium in your blood and urine (your plasma and urine electrolytes)
- the amount of sugar in your blood
- your acid-base balance (the acidity of the blood and urine)

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

Plasma-Lyte & Glucose 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.

Plasma-Lyte & Glucose Infusion contains substances that can cause metabolic alkalosis (making the blood too alkaline).

As Plasma-Lyte & Glucose Infusion contains sugar (glucose), it can cause hyperglycaemia (a high level of sugar in the blood). If this occurs, your doctor may:
- adjust the speed of infusion
- give you insulin to reduce the amount of sugar in your blood

This is particularly important if you are diabetic.

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.

Children
Plasma-Lyte & Glucose Infusion should be given with special care in children.
Newborns, especially those born premature and with low birth weight, are at increased risk of developing low or high levels of sugar in the blood (hypo or hyperglycemia), which may lead to complications.

Other medicines and Plasma-Lyte & Glucose Infusion
Tell your doctor or nurse if you are taking or have recently taken or might take any other medicines.

The following medicines **must not** be used while you are receiving an infusion of Plasma-Lyte & Glucose Infusion:
- potassium-sparing diuretics (certain water tablets, e.g. amiloride, spironolactone, triamterene, potassium canrenoate)
  (these medicines may be included in combination medicinal products. See also “You must NOT receive Plasma-Lyte & Glucose Infusion if you are suffering from any of the following conditions” at the start of this section).

The use of the following medicines **is not recommended** while you are receiving an infusion of Plasma-Lyte & Glucose Infusion:
- 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 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)
- antipsychotics
- opioids
- medicines for pain and/or inflammation (also known as NSAIDs)
- certain medicines against epilepsy
- oxytocin (drug used during the treatment of women undergoing pregnancy, childbirth and post pregnancy care)
- diuretics.

Other medicines that can affect or be affected by Plasma-Lyte & Glucose 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 & Glucose 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 or nurse for advice before taking this medicine.

You may receive Plasma-Lyte & Glucose 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. Parallel administration of medicine called oxytocin during labour may cause a decrease in sodium levels in the blood (increase the risk of hyponatraemia)
- 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 Plasma-Lyte & Glucose Infusion

You will be given Plasma-Lyte & Glucose 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 & Glucose Infusion if there are particles floating in the solution or if the pack is damaged in any way.

Plasma-Lyte & Glucose Infusion will usually be given to you through a plastic tube attached to a needle in a vein. 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 Plasma-Lyte & Glucose Infusion from a bag that has been partly used.

If you receive more Plasma-Lyte & Glucose Infusion than you should

If you are given too much Plasma-Lyte & Glucose 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
- hyperosmolarity (the blood becomes too concentrated)
- a loss of water from the body (dehydration)
- a high blood sugar level (hyperglycaemia)
- sugar in the urine (hyperglycosuria)
- an increase in the amount of urine you produce (osmotic diuresis)

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 & Glucose 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 & Glucose 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
  - 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)
  - high levels of blood potassium which can cause abnormal heart rhythm (hyperkalemia)
  - hyperglycaemia

- fits (seizures)
- hives (urticaria)
- serious allergic reaction which causes difficulty in breathing or dizziness (anaphylactoid reaction)
- low blood pressure (hypotension)
- chest discomfort
- shortness of breath (dyspnea)
- wheezing
- flushing
- hyperaemia
- feeling of weakness (asthenia)
- cold sweat
- fever (pyrexia)
- chills
- 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.

Other side effects noted with similar products

- Other manifestations of hypersensitivity/infusion reactions: a fast heartbeat (tachycardia), palpitations, chest pain, respiratory rate increased, feeling abnormal, piloerection, edema peripheral

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 (see details 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
Yellow Card Scheme
Tel: Freephone 0808 100 3352
www.mhra.gov.uk/yellowcard

5. How to store Plasma-Lyte & Glucose Infusion

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

Do not store above 30ºC.

You should not be given this medicine after the expiry date which is stated on the bag after EXP. The expiry date refers to the last day of that month.

You should not be given 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 & Glucose Infusion contains

The active substances are:
- glucose (sugar): 55.00 g per litre
- 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
- concentrated hydrochloric acid

What Plasma-Lyte & Glucose Infusion looks like and contents of the pack

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

The bag sizes are:
- 250 ml
- 500 ml
- 1000 ml

The bags are supplied in cartons. Each carton contains one of the following quantities:
- 30 bags of 250 ml
- 20 bags of 500 ml
- 10 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
Baxter Holding B.V.
Kobaltweg 49,
3542CE Utrecht,
Netherlands

Manufacturers:

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7860 Lessines
Belgium

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United Kingdom

Bieffe Medital Sabiñanigo
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22666 Sabiñanigo (Huesca)
Spain

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For information about Plasma-Lyte & Glucose or to request this leaflet in formats such as audio or large print please contact the Marketing Authorisation Holder: Tel: + 44(0)1635 206345

The following information is intended for healthcare professionals only:

Handling and Preparation

The solution should be inspected visually for particulate matter and discolouration 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.

In order to avoid potentially fatal over infusion of intravenous fluids to the neonate, special attention needs to be paid to the method of administration. When using a syringe pump to administer intravenous fluids or medicines to neonates, a bag of fluid should not be left connected to the syringe. When using an infusion pump all clamps on the intravenous administration set must be closed before removing the administration set from the pump, or switching the pump off. This is required regardless of whether the administration set has an anti-free flow device. The intravenous infusion device and administration equipment must be frequently monitored.

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

- 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 broken.
- Check the solution for clarity and absence of foreign matter. If solution is not clear or contains foreign matter, discard the solution.

2. Preparation for administration

The solution should NOT be administered through a peripheral vein.

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.

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 osmolarity 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

- 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

Chemical and physical stability of any additive at the pH of Plasma-Lyte & Glucose Infusion 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 & Glucose Infusion, 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 & Glucose Infusion is appropriate (pH 4.0 - 6.0). After addition, check for a possible colour change and/or the appearance of precipitates, insoluble complexes or crystals.

Glucose 5% solutions are not compatible with blood or red blood cells, as haemolysis and clumping have been described.

Those additives known to be incompatible should not be used.