

Package leaflet: Information for the user

Maintelyte solution for infusion

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

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.

Throughout this leaflet, Maintelyte solution for infusion will be called Maintelyte.

What is in this leaflet

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

1. What Maintelyte is and what it is used for

Maintelyte is a solution of the following substances in water:

- sugar (glucose)
- sodium chloride
- sodium acetate trihydrate
- potassium chloride
- magnesium chloride hexahydrate

Glucose is one of the body's sources of energy. This solution for infusion provides 200 kilocalories per litre. Sodium, potassium, magnesium, chloride and acetate are chemical substances found in the blood.

Maintelyte is used to provide a source of fluid and chemical substances and to give you some carbohydrate (sugar) if you are unable to eat or drink normally.

2. What you need to know before you are given Maintelyte

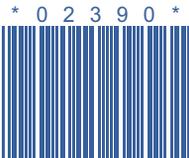
Do NOT receive Maintelyte if you are suffering from any of the following conditions

- higher levels of potassium in the blood than normal (hyperkalaemia)
- severe problems with your kidneys (renal insufficiency) with a reduction in the amount of urine produced (oliguria) or no urine at all (anuria)
- heart or lung failure (uncompensated cardiac or pulmonary failure)
- diabetes that is not adequately treated, allowing your blood sugar levels to rise above normal (uncontrolled diabetes)
- states of glucose intolerance
- unconsciousness (hyperosmolar coma). This is a type of coma that can occur if you have diabetes and do not receive enough medicine.
- higher levels of sugar in the blood than normal (hyperglycemia)
- higher levels of lactate in the blood than normal (hyperlactataemia)
- if you are allergic to potassium chloride, sodium acetate trihydrate, sodium chloride, magnesium chloride hexahydrate and glucose or any other ingredients of this medicine (listed in Section 6).

Warning and precautions

Please tell your doctor if you have or have had any of the following medical conditions.

- allergy to corn as Maintelyte contains sugar derived from corn, see section "Possible side effects"



- heart failure, severe heart rate disorder or other cardiac disease
- lung disease (respiratory failure)
- kidney failure or reduced kidney function
- high amount of fluid in the body or build up of fluid in the lungs or under the skin, particularly around the ankles
- high blood pressure
- high blood pressure during pregnancy (pre-eclampsia or eclampsia)
- a disease that causes high levels of a hormone called aldosterone (aldosteronism)
- any other condition associated with the body retaining too much sodium, such as treatment with steroids (See also below, “Other medicines and Maintelyte”).
- any condition that means you are more likely to have high blood levels of potassium such as:
 - kidney failure
 - disease of the adrenal gland (adrenocortical insufficiency)
 - rapid loss of water from the body e.g. due to vomiting or diarrhoea
 - severe burns or other causes of extensive tissue damage
- low blood calcium levels
- a disease that causes progressive muscle weakness (myasthenia gravis)
- a recent operation involving nerve and muscle blocking medicines (neuromuscular block) used in surgical operations and controlled by your anaesthetist
- disturbances in the pH of the blood
- head injury within the past 24 hours - Maintelyte” should not be used.
- high pressure within the skull
- stroke due to a blood clot in the brain (ischaemic stroke)
- malnourished, if you have been starving or eaten very badly for some time
- diabetes or impaired glucose tolerance
- 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:

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

As Maintelyte contains sugar (glucose), it can cause a high level of sugar in the blood (hyperglycemia). This is particularly important if you have diabetes. If this occurs, your doctor may:

- adjust the speed of infusion
- give you insulin to reduce the amount of sugar in your blood.

If long-term treatment with Maintelyte 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.

Children

Maintelyte must be given with special care in children and close monitoring is required. In newborns, especially born premature and with low birth weight are at increased risk of developing a too low or too high level of sugar in the blood due to infusion of glucose solutions. Low level of sugar in the newborn can cause prolonged seizures, coma and brain damage. High level of sugar has been associated with bleeding into the brain, late onset bacterial and fungal infection, infection in the intestinal track, affects eyes, lungs problems, prolonged length of hospital stay, and death.

Pediatric patients should be closely monitored. In cases where normal regulation of the water content of the blood is disturbed due to increased secretion of Antidiuretic Hormone (ADH), the infusion of fluids with a low concentration of

sodium chloride may result in a low level of sodium in the blood (hyponatraemia). This can lead to headache, nausea, seizures, lethargy, coma, swelling of the brain and death; therefore these symptoms are considered a medical emergency.

Other medicines and Maintelyte

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

The use of the following medicines is **not recommended** while you are receiving an infusion of Maintelyte:

- neuromuscular blocking agents (e.g. tubocurarine, suxamethonium and vecuronium) which are medicines used in surgical operations and are controlled by your anaesthetist.

Other medicines that can affect or be affected by Maintelyte:

- anti-inflammatory medicines (corticosteroids)
- an anti-inflammatory medicine used to treat stomach ulcers (carbenoxolone)
- certain water tablets called potassium-sparing diuretics (e.g. amiloride, spironolactone, triamterene)
- 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)
- acidic medicines including:
 - salicylates (used to treat inflammation) (aspirin)
 - barbiturates (sleeping tablets)
 - lithium (used to treat psychiatric illnesses)
- alkaline medicines including:
 - sympathomimetics (such as ephedrine and pseudoephedrine e.g. used in cough preparations)
 - stimulants (such as quinidine, dexamphetamine sulphate (used to treat ADHD)) phenfluramine hydrochloride (used to treat overweight)).

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

- water tablets (diuretics)
- medicines for pain and/or inflammation (also known as NSAIDs)
- antipsychotics
- medicines used to treat depression (selective serotonin reuptake inhibitors)
- medicines that produce morphine-like effects (opioids)
- certain medicines used to treat epilepsy (antiepileptics)
- a hormone called oxytocin (causes uterus to contract)
- certain medicines used to treat cancer (chemotherapy).

Maintelyte 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 you are given this medicine. He/she will decide if you can be given Maintelyte when you are pregnant or breast-feeding.

Driving and using machines

This medicine does not affect your ability to drive or use machines.

3. How you will be given Maintelyte

You will be given Maintelyte 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 and clinical condition and concomitant treatment. Your doctor may check the levels of salts (electrolytes) and sugar (glucose) in your blood.

You should NOT be given Maintelyte if there are particles floating in the solution or if the package is damaged in any way.

Maintelyte 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.

You should NOT be given Maintelyte into the skin (subcutaneously).

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

Because of the presence of glucose, you should NOT be given this solution through the same infusion equipment as whole blood (blood transfusion). This can damage the red blood cells or cause them to clump together.

If you receive more Maintelyte than you should

If you are given too much Maintelyte (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 (oedema) in the tissues causing swelling
- a high blood sugar level (hyperglycemia)
- 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

- mood changes
- tiredness
- shortness of breath
- stiffness of muscles
- twitching of the muscles
- spasm of muscles (tetany)
- elevated level of magnesium in blood.

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 Maintelyte and an overdose occurs, that medicine may also cause symptoms. You should read the Package Leaflet of the added medicine for a list of possible symptoms.

If you stop receiving Maintelyte

Your doctor will decide when to stop the 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. The frequency of the side effects is *not known (cannot be estimated from the available data)*

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)
- hypersensitivity reactions, including a serious allergic reaction called anaphylaxis are potential manifestation in patients with allergy to corn.

You will be given treatment depending on the symptoms.



Other side effects are:

- reactions due to the administration technique:
 - fever
 - infection at the site of infusion
 - local pain or reaction (redness or swelling) at the site of infusion
 - irritation or 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) sometimes accompanied by an inflammation. This causes pain, swelling or redness.
 - escape of the infusion solution into the tissues around the vein (extravasation).
- high levels of blood potassium which can cause abnormal heart rhythm (hyperkalemia)
- a high blood sugar level (hyperglycemia)
- build up of excessive fluid in the body (hypervolemia)
- disturbances of the concentration of salts in the blood (electrolyte disturbance)
- fits (seizures)
- low levels of sodium in the blood (hyponatraemia)
- swelling of the brain that may cause brain injury (hyponatraemic encephalopathy).

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 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 methods 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 or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland: HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

Malta: ADR Reporting - Website: www.medicinesauthority.gov.mt/adrportal

5. How to store Maintelyte

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

Maintelyte should NOT be given to you after the expiry date which is stated on the bag after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

You should not be given Maintelyte 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 Maintelyte contains

The active substances are:

- Glucose (as monohydrate) 50 g per litre
- Sodium Chloride: 1 g per litre
- Sodium acetate trihydrate: 3.13 g per litre
- Potassium Chloride: 1.50 g per litre
- Magnesium chloride hexahydrate: 0.30 g per litre

The other ingredients are:

- concentrated hydrochloric acid (for pH adjustment)
- water for injections

What Maintelyte looks like and contents of the pack

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

The bag size is 1000 ml.

The bags are supplied in cartons. Each carton contains 10 bags of 1000 ml.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

United Kingdom:

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

Ireland and Malta:

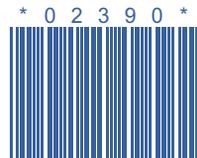
Baxter Holding B.V.
Kobaltweg 49,
3542CE Utrecht,
Netherlands

Manufacturers:

Bieffe Medital Sabiñàigo
Ctra de Biescas-Senegüé-Sorripas
22666 Sabiñàigo (Huesca)
Spain

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For information about Maintelyte or to request
this leaflet in formats such as audio or large print
please contact the Marketing Authorisation Holder
Tel: +44(0)1635206345.



Maintelyte solution for infusion

The following information is intended for healthcare professionals only:

Handling and Preparation

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

Do not remove unit from overwrap until ready for use.

The inner bag maintains the sterility of the product.

Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before the administration of the fluid from the secondary container is completed.

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.

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 solution.
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

The solution must NOT be administered subcutaneously.

Some additives may be incompatible

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.

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 Maintelyte 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

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

This solution must not be mixed with other medicinal products in the absence of compatibility studies.

The Instructions 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 Maintelyte (pH 4.5 - 6.5)

Maintelyte solutions are not compatible with blood or red blood cells, as clotting has been reported.

Additives known to be incompatible should not be used.

