PACKAGE LEAFLET: INFORMATION FOR THE USER

Mannitol Baxter Viaflo 150 mg/ml Solution for Infusion
mannitol

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 pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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:

1. What Mannitol Baxter Viaflo is and what it is used for

Mannitol Baxter Viaflo is a solution of mannitol in water.
Mannitol Baxter Viaflo is used to:
- Produce an increase in your urine production (diuresis) when your kidneys are not working properly
- Reduce the pressure within the skull caused by an accumulation of liquid within the brain (oedema) or after a head injury
- Reduce pressure in the eye (intraocular pressure)
- Treat certain types of poisoning or drug overdose

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

Do not receive Mannitol Baxter Viaflo
- If you are allergic to mannitol.
- If you have a high concentration of salts in your blood.
- If you are severely dehydrated.
- If your kidneys cannot produce urine.
- If you have severe heart disease (heart failure).
- If you have a build-up of fluid in the lungs (pulmonary oedema) associated with heart failure
- If you have bleeding inside the skull (active intracranial bleeding) or if you have some type of recent, severe head injury.
- If you fail to respond to test dosing, which your doctor or nurse will give you (see section 3).
- If your kidney function worsens after initiating mannitol treatment.

If you are unsure whether you are affected by any of the conditions above, please ask your doctor.

Warnings and precautions

Talk to your doctor before receiving Mannitol Baxter Viaflo
- If you have kidney disease or poor kidney function.

- If you are receiving medicines which may be harmful to your kidneys (for example, certain antibiotics or anticancer medicines).
- If you are severely dehydrated (a loss of water from the body, e.g. due to vomiting, diarrhoea, profuse sweating or certain medications). Symptoms will include dry mouth and dizziness.
- If you have been told by your doctor you have a low level of sodium (salt) in your blood (hyponatremia).
- If you have an allergy to mannitol (as mannitol is found in nature and is used in other medical products, you may have developed sensitivity to this substance without having received intravenous treatment with mannitol). The infusion must be stopped if any signs of hypersensitivity develop, see section 4.

When monitoring is required your doctor may want to carry out tests to ensure that your dose is sufficient. These tests may include:
- How well your heart, lungs and kidneys are working.
- The amount of liquid you are receiving.
- The amount of urine you are producing.
- The blood pressure in the veins returning blood to your heart (central venous pressure).
- The amount of chemicals, such as sodium and potassium, in your blood and urine (electrolytes).
- The acidity of your blood and urine (your acid-base balance).

This solution should not be given through the same needle as blood transfusion. This can damage the red blood cells or cause them to clump together.

Other medicines and Mannitol Baxter Viaflo

Tell your doctor or nurse if you are using, have recently used or might use any other medicines.

The following medicines are known to affect or be affected by Mannitol Baxter Viaflo. Please tell your doctor if you are taking any of these medicines:

- Diuretics (water tablets, to increase the amount of urine you produce).
- Ciclosporin (used to prevent rejection of a transplant).
- Lithium (used for mental disorders).
- Aminoglycoside (a type of antibiotic).
- Depolarising neuromuscular blocking drugs (used during anaesthesia to cause muscle paralysis). These will be controlled by your anaesthetist.
- Oral anticoagulants (medicines to thin the blood, for example warfarin).
- Digoxin (a heart medicine).

Mannitol Baxter Viaflo with food, drink and alcohol
You should ask your doctor about what you can eat or drink.

Pregnancy and breast-feeding
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.

It is not known whether mannitol could affect your unborn baby or your pregnancy. It is also not known whether mannitol could reach your baby through your breast milk. Your doctor will therefore only give you Mannitol Baxter Viaflo, during pregnancy or breast-feeding, if it is clearly needed.

Driving and using machines
There is no information of the effects of this product on the ability to drive or operate other heavy machinery.

3. How you will be given Mannitol Baxter Viaflo

Your doctor will decide on how much you need and when it is to be given. The doctor(s) make the decision based on your age, weight, medical condition and the medicine(s) you are taking. Mannitol Baxter Viaflo

will usually be given to you through an infusion line that accesses your vein. If your kidneys are not working properly, your doctor may give you a small amount of the solution as a test dose. The amount of urine you produce will then be measured. If your kidneys don't produce more urine as a response to the test dose, you will be given a different treatment.

Mannitol Baxter Viaflo can also be used in children and the elderly (over 65 years of age). Your doctor will adjust the dose as needed.

You should NOT be given Mannitol Baxter Viaflo if there are particles floating in the solution or if the pack is damaged in any way.

If you receive more Mannitol Baxter Viaflo than you should
If you are given too much Mannitol Baxter Viaflo (over-infusion) or if it is given too fast, this may lead to the following symptoms:
- Too much blood in the blood vessels (hypervolaemia). The symptoms include swelling in the arms and legs (peripheral oedema), difficulty breathing (pulmonary oedema and dyspnea), fluid in the abdomen (ascites) and imbalances of chemicals in your body (electrolytes imbalance).
- Your blood may become too acid (acidosis).
- Headache.
- Feeling sick (nausea)
- Shivering.
- Confusion.
- Tiredness.
- Fits (seizures).
- Reduced consciousness (stupor) and unconsciousness (coma).
- Kidney failure (acute renal failure).

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 medication has been added to Mannitol Baxter Viaflo you should read the Package Leaflet of the added medicine for a list of possible symptoms.

Stopping your Mannitol Baxter Viaflo

Your doctor will decide when to stop giving you this infusion.

If you have any further questions on the use of this medicine, ask your doctor.

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) reaction called anaphylactic shock:
- Difficulty breathing.
- A low blood pressure (hypotension).
- Swelling of the skin of the face and throat.
- Hives (urticaria).
- Skin rash.

You will be given treatment depending on the symptoms.

Other side effects that you may experience include:

- Damage to the kidneys, which might cause difficulty with passing water or decreased or increased amount of urine being passed.
- Presence of blood in the urine.
- Heart failure.
- High blood pressure.
- A rapid or irregular heartbeat (palpitations, cardiac arrhythmia).
- Excess fluid in the lungs causing shortness of breath.
- Coma, convulsions, confusion or tiredness (lethargy) due to damage to the central nervous system.
- Swelling of ankles, fingers or face due to build up of fluid in the body.
- Dehydration.
- Increased or decreased amounts of potassium and/or sodium in your blood.
- Dryness of the mouth, thirst.
- Nausea, vomiting.
- Feeling sick (malaise)
- Increased amounts of acid in your blood (metabolic acidosis, see “If you receive more Mannitol Baxter Viaflo than you should” in section 3).
- Chest pain.
- Chills, fever.
- An increase in pressure within the skull (raised intracranial pressure), causing headaches, feeling sick (nausea), being sick (vomiting), back pain, blurred vision and other changes to your sight, such as difficulty moving your eyes (ocular palsy).
- Dizziness, headache
- Fatigue and weakness (asthenia)
- Cramps.
- Blurred vision.
- Runny nose.
- Skin necrosis.
- Reactions due to the administration technique may include inflammation, pain, itching, rash or redness at the infusion site or along the path of the vein.
- Escape of the infusion solution into the tissues around the vein (extravasation). This might cause swelling and pain at the injection site. In severe cases, the blood flow will be decreased and the surrounding tissue will be injured (compartment syndrome).

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

To be completed nationally.

5. How to store Mannitol Baxter Viaflo

This product should not be refrigerated or frozen.

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

Do not remove Mannitol Baxter Viaflo from the outer plastic bag until it is to be used.

Mannitol Baxter Viaflo 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.

After opening, with or without additives:
From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.

You should not be given Mannitol Baxter Viaflo 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 Mannitol Baxter Viaflo contains

The active substance is mannitol.
The only other ingredient is water for injections.
Each 1000 ml of solution contains 150 grams of mannitol.

What Mannitol Baxter Viaflo looks like and contents of the pack

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

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

The bags are supplied in cartons. Each carton contains one of the following quantities:
- 50 bags of 100 ml
- 60 bags of 100 ml
- 30 bags of 250 ml
- 20 bags of 500 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder :
MAH To be completed nationally

Manufacturers :
Baxter S.A.
Boulevard R. Branquart, 80
7860 Lessines
Belgium

Bieffe Medital S.A.
Ctra de Biescas-Senegüé
22666 Sabiñànigo (Huesca)
Spain

Baxter Healthcare S.A.
Moneen Road
Castlebar – County Mayo
Ireland

This leaflet was revised in 15 December 2021
To be completed nationally

The following information is intended for medical or healthcare professionals only:

<u>Handling and Preparation</u>

Use only if the solution is clear, without visible particles or discoloration and if the container is undamaged.
Administer immediately following the insertion of infusion set which includes a final in-line filter because of the potential for mannitol crystals to form.
Hyperosmolar mannitol solutions may cause vein damage. The osmolarity of the solution should be considered.

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.
The solution should be administered through a sterile and non-pyrogenic administration set which includes a filter and using an aseptic technique. The equipment should be primed with the solution in order to prevent air entering the system.
Additives may be incompatible with Mannitol Baxter Viaflo.
Additives may be introduced before infusion or during infusion through the re-sealable medication port.
Thorough and careful aseptic mixing of any additive is mandatory. Solutions containing additives should be used immediately and not stored.
Adding other medications or using an incorrect administration technique may cause febrile reactions due to possible introduction of pyrogens. In case of an adverse reaction, infusion must be stopped immediately.

Mannitol solutions may crystallize when exposed to low temperatures. At higher concentrations, the solutions have a greater tendency to crystallize. Inspect for crystals prior to administration. If crystals are visible, re-dissolve by warming the solution up to 37°C, followed by gentle agitation. Solutions should not be heated in water or in a microwave oven due to the potential for product contamination or damage. Allow the solution to cool to room or body temperature before re-inspection for crystals and use.

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 impaired.
c. Check the solution for limpidity and absence of foreign matters. If solution is not clear or contains foreign matters, discard the solution.

2. Preparation for administration

Use sterile material for preparation and administration.
a. Suspend container from eyelet support.
b. Remove plastic protector from outlet port at bottom of container:
   - grip the small wing on the neck of the port with one hand,
   - grip the large wing on the cap with the other hand and twist,
   - the cap will pop off.
c. Use an aseptic method to set up the infusion.
d. Attach administration set. Refer to complete directions accompanying set for connection, priming of the set and administration of the solution.

3. Techniques for injection of additive medications

Warning: Additives may be incompatible *(see Paragraph 5 "Incompatibilities of additive medications" below).*

To add medication before administration

a. Disinfect medication port.

b. Using syringe with 19 gauge (1.10 mm) to 22 gauge (0.70 mm) needle, puncture re-sealable medication port and inject.
c. Mix solution and medication thoroughly. For high-density medication such as potassium chloride, tap the ports gently while ports are upright and mix.

Caution: Do not store bags containing added medications.

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

4. In-use shelf-life: Additives
Chemical and physical stability of any additive at the pH of Mannitol 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.

5. Incompatibilities of additive medications
Mannitol Baxter Viaflo should not be administered simultaneously with, before, or after administration of blood through the same infusion equipment, due to risk of pseudoagglutination. Incompatibility of the medicinal product to be added with the solution in the Viaflo container must be assessed before addition.

The Instructions for Use of the medicinal product to be added must be consulted.
Before adding a medicinal product, verify it is soluble and stable in water at the pH of the mannitol solution (4.5 to 7.0) As a guide, cefepime, imipenem, cilastin and filgrastim are incompatible with mannitol solutions, but this list is not exhaustive.
The addition of potassium or sodium chloride to Mannitol Baxter Viaflo may cause precipitation of mannitol.