Baxter

PACKAGE LEAFLET: INFORMATION FOR THE USER

Mannitol 10% Solution for infusion BP

Mannitol 10% Infusion
Active substance: mannitol

This medicine is called `Mannitol 10% Solution for Infusion BP´ but will be referred to as `Mannitol 10% Infusion´ throughout the remainder of this leaflet.

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 10% Infusion is and what it is used for

Mannitol 10% Infusion is a solution of mannitol in water.

Mannitol 10% Infusion is used to:

- Produce an increase in your urine production (a diuresis), when your kidneys are not working properly, and to reduce the amount of water in your body.
- 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 do you need to know before you are given Mannitol 10% Infusion

Do not receive Mannitol 10% Infusion if you are suffering from any of the following conditions:

- Allergy to mannitol (which is found naturally in some fruit and vegetables and may be added to some cosmetics, food-stuffs and medicines, during manufacturing). You may have developed sensitivity to this substance, without

having received intravenous treatment with mannitol. If you are unsure about this, ask your doctor.

- If you have a high concentration of solutes in your blood (hyperosmolarity).
- Failure of the kidneys to produce urine. 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 or diarrhoea, profuse sweating or certain medications). Symptoms will include dry mouth and dizziness.
- 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 types of recent, severe head injury.

Warnings and precautions

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

- 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.
- A low level of sodium (salt) in your blood (hyponatremia).

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 a blood transfusion. This can damage the red blood cells or cause them to clump together.

Other medicines and Mannitol 10% Infusion

Tell your doctor or pharmacist 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 10% Infusion. 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).
- Aminoglycosides (a type of antibiotic).
- Depolarising neuromuscular blocking drugs (drug 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 10% Infusion 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 10% Infusion, during pregnancy or breast-feeding, if it is essential.

Driving and using machines

Ask your doctor or nurse for advice before driving or using machines.

3. How you will be given Mannitol 10% Infusion

Your doctor will decide on how much you need and when it is to be given. The dose to be given is always governed by your individual requirements. Mannitol 10% Infusion will usually be given to you through a plastic tube attached to a needle, in a vein. If your kidneys are not working properly, your doctor may give you a test dose of the infusion. The amount of urine you produce will then be measured.

Mannitol 10% Infusion can also be used in children and in the elderly (over 65 years of age). Your doctor will adjust the dose as necessary.

You should NOT be given Mannitol 10% Infusion if there are particles floating in the solution or if the pack is damaged in any way.

Crystals may form in the solution when exposed to low temperatures. Your doctor or nurse will ensure that these crystals have been resorbed before they administer the solution.

If you receive more Mannitol 10% Infusion than you should

If you are given too much Mannitol 10% Infusion (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), imbalances of the chemicals in your body (electrolytes imbalance) and 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 10%, you should read the Package Leaflet of the added medicine for a list of possible symptoms.

Stopping your Mannitol 10% 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.

4. Possible side effects

Like all medicines, Mannitol 10% Infusion can cause side effects, although not everybody gets them.

Tell your doctor or nurse immediately if you have any of the following symptoms.

These may be signs of a very severe or even fatal allergic reaction called anaphylactic shock:

- Difficulty breathing.
- A low blood pressure.
- Swelling of the skin of the face and throat.
- Hives.
- Skin rash.

Tell your doctor or nurse as soon as possible if you have any of the following symptoms:

- An increase in pressure within the skull, causing headaches, feeling sick, being sick, back pain, blurred vision and other changes to your sight, such as difficulty moving your eyes.
- Coma, convulsions, confusion or tiredness (lethargy) due to damage of the central nervous system.
- Heart failure
  - Excess fluid on the lungs, causing shortness of breath,
  - Swelling of ankles, fingers or face, due to build up of fluid in the body,
  - Fatigue and weakness.
- Damage to the kidneys, which might cause difficulty with passing water or a decreased or increased amount of urine being passed.
- Other hypersensitivity infusion reactions include high blood pressure, chills, fever, sweating, cough, painful or stiff muscles, itchy skin, nausea, vomiting, and headache.

You will be given treatment depending on the symptoms.

Other side effects, which you may experience, include:

- Dehydration.
- Dryness of the mouth.
- Thirst.
- Nausea, feeling sick.
- Feeling numbness or tingling.
- Headache.
- Dizziness.
- A rapid or irregular heartbeat.
- Chest pain.
- Bloating, constipation.
- Cramps.
- Blurred vision.
- Runny nose.
- Hives.
- Pain.
- Skin coloration (redness).
- Swelling or fluid accumulation.
- Blisters (may be filled with clear fluid or blood).
- Skin turns dark red, purple, or black.
- Abnormal sensation (tingling, prickling, burning, etc.).
- Numbness or loss of sensation.
- Vomiting.
- Fever.
- Chills.

- The reactions due to administration technique may include swelling, 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. This might cause swelling and pain at the injection site. In severe cases, blood flow will be decreased and the surrounding tissue will be injured.

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 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

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.

5. How to store Mannitol 10% Infusion

This product should not be refrigerated or frozen.

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

Do not remove Mannitol 10% Infusion from the outer plastic bag until it is to be used.

Mannitol 10% Infusion 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 10% 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 Mannitol 10% Infusion contains

The active substance is mannitol.
The only other ingredient is water for injections.
Each 1000 ml of solution contains 100 grams of mannitol.

What Mannitol 10% Infusion looks like and contents of the pack

Mannitol 10% 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

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

- 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 :

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

Manufacturers for Great Britain:

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

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For information about Mannitol 10% 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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MANNITOL 10% W/V SOLUTION FOR INFUSION BP

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

Handling and Preparation

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. Check product's osmolarity before administration.

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 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 incompatible with Mannitol 10% Infusion.

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 temperature. 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. Only dry heat (for example, a warming cabinet) should be used. 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 10% Solution for Infusion 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 an example, cefepime, imipenem, cilastin and filgrastim are incompatible with mannitol solutions, but this list is not exhaustive. In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

The addition of potassium or sodium chloride to Mannitol 10% may cause precipitation of mannitol.

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