Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor or pharmacist
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

Throughout this leaflet Mannitol Intravenous Infusion EP 20% w/v will be called Mannitol 20% Infusion.

**In this leaflet:**
1. What Mannitol 20% Infusion is and what it is used for
2. Before you are given Mannitol 20% Infusion
3. How you will be given Mannitol 20% Infusion
4. Possible side effects
5. How Mannitol 20% Infusion is stored
6. Further information

**1. What Mannitol 20% Infusion is and what it is used for**

Mannitol 20% Infusion is a solution of mannitol in water. Mannitol is an osmotic diuretic. Osmotic diuretics act in the kidney to make it produce more urine. This will reduce the amount of water in your body. Mannitol 20% Infusion is given by infusion into a vein.

**2. Before you are given Mannitol 20% Infusion**

You must NOT receive Mannitol 20% Infusion if you are suffering from any of the following conditions:

- if you are allergic to mannitol or any of the other ingredients of Mannitol 20% Infusion. See section 6.
- if you have a high concentration of salts in your blood. This is due to an excessive loss of water from the blood and can be caused by problems such as:
  - prolonged, profuse sweating
  - excess treatment with certain medicines such as water tablets
  - kidney disease.

Turn over leaflet for further information.
continues from page 1

• if you are severely dehydrated e.g. due to vomiting or diarrhoea. Severe dehydration gives you a dry mouth and makes you very thirsty
• if it is known that your kidneys cannot produce urine
• if you have severe heart failure
• if you have a build up of fluid in the lungs associated with heart failure
• if you have bleeding inside the skull, except during an operation on the skull
• if the natural protective barrier between the blood vessels in your head and your brain is damaged. This could occur, for example, after severe injury to the head (such as a fracture of the skull).

Your doctor will take special care when giving you Mannitol 20% Infusion

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

• 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). Your doctor will know if any of the medicines you are taking could affect your kidneys
• a medical condition where there is inadequate supply of blood to the tissues
• heart failure
• a low level of salt in your blood
• not enough water in your body
• a low volume of blood in your blood vessels.

When you are given this infusion, your doctor will regularly monitor:

• 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
• the amount of chemicals such as sodium and potassium in your blood and urine.

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.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Some medicines can affect or be affected by Mannitol 20% Infusion. If you are taking any of these medicines, it may be necessary to change the dose.

The following medicines are known to affect or be affected by Mannitol 20% 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 (antibiotics such as amikacin, gentamicin and streptomycin)
• depolarising neuromuscular blocking drugs. These drugs are also known as muscle relaxants and may be given to you by your anaesthetist during an operation
• oral anticoagulants (medicines to thin the blood, for example warfarin)
• digoxin (a heart medicine)
• methotrexate (a medicine used in the treatment of cancer and certain diseases of the immune system).

Certain medicines must not be added to the bag of Mannitol 20% Infusion. These include:

• Potassium
• Sodium
• Cefepime (an antibiotic)
• Imipenem (an antibiotic)
• Cilastin (a substance given with some antibiotics to help them work better)
• Filigratim (a medicine used to increase the number of white cells in the blood).
Using Mannitol 20% Infusion with food and drink
You should ask your doctor about what you can eat or drink.

Pregnancy and breast-feeding
Ask your doctor or pharmacist before taking any medicine.
Please tell your doctor if you are pregnant or breast-feeding.
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 20% Infusion during pregnancy or breast-feeding if it is essential.

Driving and using machines
Mannitol 20% Infusion does not affect your ability to drive or use machines.

3. How you will be given Mannitol 20% Infusion
Mannitol 20% Infusion will be given to you by a doctor or nurse. Your doctor will decide on how much you need and when it is to be given. 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 Mannitol 20% Infusion if there are particles in the solution or if the pack is damaged in any way.
Mannitol 20% 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.
The normal speed of infusion is 30 to 50 ml per hour. This means that the infusion of a half-litre bag would take at least 10 hours.
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. If your kidneys do not respond well enough, you will be given a different treatment.
Mannitol 20% Infusion can also be used in children and in the elderly (over 65 years of age). Your doctor will adjust the dose as necessary.
If you receive more Mannitol 20% Infusion than you should
If you are given too much Mannitol 20% Infusion or it is given too fast, this may lead to the following symptoms:
• too much blood in the blood vessels
• your blood may become too acid. The symptoms of acidosis include drowsiness, feeling and being sick and acetone smelling breath
• headache
• feeling sick
• shivering, but without fever.
• confusion
• tiredness
• fits
• reduced consciousness and unconsciousness.
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. Your doctor will also make the necessary examinations. You may need hospital treatment if the symptoms are dangerous.
If a medication has been added to Mannitol 20% Infusion before over-infusion occurs, that medicine may also cause symptoms. You should read the Patient Information Leaflet of the added medicine for a list of possible symptoms.
Stopping your Mannitol 20% Infusion
Your doctor will decide when to stop giving you this infusion.
If you have any further questions on the use of this product, ask your doctor.

4. Possible Side Effects
Like all medicines, Mannitol 20% Infusion 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:

– swelling of the skin of the face and throat
– difficulty breathing
– a low blood pressure
– skin rash
– hives.

You will be given treatment depending on the symptoms.

The other side effects are listed according to their frequencies.

**Uncommon** (occurring in less than 1 of every 100 patients but in more than 1 of every 1,000 patients)

- too much or too little liquid in the body.
  - Your fluid balance will be monitored during treatment
- imbalance in the concentrations of chemicals in the blood. Your doctor will monitor this during treatment
- a low blood pressure. Your blood pressure will be measured during treatment
- inflammation of the vein with redness, swelling and pain along the path of the vein.

**Rare** (occurring in less than 1 of every 1,000 patients but in more than 1 of every 10,000 patients):

- not enough water in the body. Symptoms include thirst, loss of appetite, fatigue and chills
- fluid collecting under the skin, usually around the ankles
- headache
- convulsions
- dizziness
- an increase in pressure within the skull
- blurred vision
- an irregular heartbeat
- a high blood pressure. Your blood pressure will be measured during treatment
- a build up on fluid in your lungs
- runny/itchy nose
- dryness of the mouth
- death of an area of skin
- thirst
- feeling sick
- vomiting
- hives
- cramps
- production of a large volume of urine
- damage to the kidney caused by medicines like mannitol. This will be diagnosed during tests on your urine
- an inability to pass water
- chills
- chest pain
- fever.

**Very rare** (occurring in less than 1 of every 10,000 patients)

- heart failure associated with fluid on the lungs and swelling of the ankles
- sudden onset of kidney failure, seen by a marked decrease in urine production.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse.

5. How Mannitol 20% Infusion is stored

VIAFLEX containers should be stored within their overpouch at a temperature between 20°C – 30°C
Keep out of the reach and sight of children.
Do not remove Mannitol 20% Infusion from the outer plastic bag until it is to be used.
Mannitol 20% Infusion should NOT be given to you after the expiry date shown on the bag. The expiry date refers to the last day of that month.
You should not be given Mannitol 20% Infusion if there are particles in the solution or if the unit is damaged in any way.

6. Further Information

This leaflet does not contain all the information about this medicine. If you have any questions or are not sure about any thing, ask your healthcare professional.
What Mannitol 20% Infusion contains

The active substance is mannitol.

The other ingredients are:

• water for injections
• sodium hydroxide.

Each 1000 ml of solution contains 200 grammes of mannitol.

What Mannitol 20% Infusion looks like and contents of the pack

• The solution is supplied in a plastic VIAFLEX infusion bag made from PVC. The bag contains either 200 ml, 250 ml, 500 ml or 1000 ml and is sealed in a protective plastic overpouch.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder:

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

Send all enquiries to this address.

Mannitol 20% Infusion can be made at any of these addresses:

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

Baxter S.A.
Boulevard René Branquart, 80
7860 Lessines
Belgium

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

This leaflet was last approved in 11/2009
Mannitol Intravenous Infusion EP 20% w/v

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

Handling and Preparation
The solution for infusion should be visually inspected prior to use.
Use only if the solution is clear, without visible particles and if the container is undamaged.
Administer immediately following the insertion of the air connector.
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 introduced before infusion or during infusion through the re-sealable medication port. 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.

In cooler temperatures the mannitol may form crystals. Redissolve any crystallised mannitol by warming in a water bath heated to 50 – 70ºC, agitating the solution vigorously periodically. Cool to 37ºC before infusion.
Discard after single use.
Discard any unused portion.
Do not reconnect partially used bags.

Preparation for Administration
The VIAFLEX container has an outlet port designed for an administration set with a short single connector. If an administration set with a combined air inlet/liquid path connector has to be used, ensure the air inlet tube is always clamped off.

1. Opening
   a. Remove the protective overpouch by tearing down from notch and remove container.
   b. Carefully straighten hanger and ports, if necessary.
   c. Squeeze container and inspect for minute leaks and examine solution for visible particles or cloudiness by viewing along seam.
   d. Discard unit if leaks, particles or cloudiness are evident.

2. Preparation for administration
   Use sterile material for preparation and administration.
   a. Suspend container from base eyelet support.
   b. Use an aseptic technique to prepare the administration set.
   c. Remove blue protector from outlet port and insert set connector well into port.
   d. Prime set and regulate administration as required.
   e. If administration set becomes blocked do not pump contents back into container but replace equipment.
   f. Discard any unused portion and equipment after use. Do not store or reconnect partly used containers.

3. Techniques for injection of additive medications
   The VIAFLEX container has a second port with a self-sealing rubber medication port designed for the addition of medication using a syringe. This is the only port for adding medication.
   Warning: Additives may be incompatible.
   To add medication before administration
   a. Swab the medication port with the appropriate anti-bacterial fluid in line with current recommended practice and procedure.
   b. Using a syringe with a 20-22 gauge needle, puncture re-sealable medication port and inject. Do not leave the syringe and needle in the port once the medication has been injected.
c. Shake and squeeze the VIAFLEX container so that the solution and medication are thoroughly mixed. For high density medications such as potassium chloride, squeeze both ports while upright and invert the container several times while shaking and squeezing to ensure thorough mixing.

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 a syringe with a 20-22 gauge 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.

F. Return container to in use position, re-open the clamp and continue administration.

Cautions

a. Do not vent.

b. Do not administer unless the solution is clear and container undamaged.

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

d. Discontinue infusion if adverse reaction occurs.

e. Rapid infusion may be harmful.

f. It is recommended that the intravenous administration set be replaced at least once every 24 hours. Details of the use of the set can be recorded – record labels are available from Baxter Healthcare Ltd.

4. In-use shelf life

Chemical and physical stability of any additive at the pH of the Mannitol 20% Infusion in the VIAFLEX 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

Mannitol 20% 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.

WARNING: Additives may be incompatible. The introduction of additives to any solution, regardless of type of container, requires special attention to assure that no incompatibilities result.

While some incompatibilities are readily observed, it is important to be aware that subtle physical, chemical and pharmacological incompatibilities can occur. The medical literature, the additive package insert and other available sources of information should be reviewed for a more thorough understanding of possible incompatibility problems.

If, in the informed judgment of the physician, it is deemed advisable to introduce additives into this solution, aseptic technique must be employed.

It is recommended that medication is added only under Pharmaceutical supervision.

Do not add medication before hanger and ports have been straightened and the container inspected.

Do not store solutions with added medication.

Before adding a drug, verify it is soluble and stable in water at the pH of the Mannitol 20% Infusion (4.5 to 7.0).

As a guide, the following medications are incompatible with Mannitol 20% Infusion (non-exhaustive listing)

- Cefepime
- Imipenem
- Cilastin
- Filgrastim.

The addition of potassium or sodium chloride to Mannitol 20% Infusion may cause precipitation of mannitol.

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