PACKAGE LEAFLET:
Information for the user

MANITOL

Solution for infusion – 200 mg / ml (20 %)
(Mannitol)

Read all of this leaflet carefully before you start taking this medicine.
- 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 any of the side effects gets serious or if you notice side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet

1. WHAT MANITOL IS AND WHAT IT IS USED FOR

Mannitol is an osmotic diuretic. Although an isomer of sorbitol, it has a lower energetic value, since it is eliminated in a larger amount from the organism before its metabolism can take place. During parenteral administration, mannitol raises the osmotic pressure of plasma and thus draws water out of body tissues by producing osmotic diuresis. During the use as an osmotic diuretic, mannitol is administered parenterally.

Manitol - solution for infusion is indicated in the:
- prevention and/or treatment of oliguria in patients with renal failure;
- reduction of raised intracranial pressure and in the treatment of cerebral oedema;
- short - term treatment of glaucoma, particularly to reduce the intraocular pressure, prior to ophtalmic surgery;
- treatment of toxicity (increased excretion of toxic substances).

Your doctor may have prescribed Manitol for another reason. Ask your doctor if you want to know why you are taking this medicine.

2. BEFORE YOU TAKE MANITOL

Do not take Manitol if you:
- are hypersensitive to the active substance;
- have pulmonary congestion or pulmonary oedema;
- have intracranial haemorrhage (except during craniotomy);
- have congestive heart failure;
- have anuria;
- have severe dehydration.

Mannitol solution should never be mixed with blood for transfusion or inserted in the same set by which blood is being infused, because erythrocytes agglutinate.

Take special care with Manitol

The renal and cardiovascular function should be examined.
Special care should be taken in patients with severe renal failure (in these patients initially is given a test dose to check the function of the kidneys).
During infusion of mannitol solution, careful monitoring of fluid balance, electrolytes, and of the vital signs is necessary to prevent fluid and electrolyte imbalance, including circulatory overload and tissue dehydration.
The solution may crystallise during storage, particulary at low temperatures; crystals should be dissolved by warming the bottles or the plastic bags before use.

Taking other medicines

Concomitant treatment with other medicines may affect or be affected by Manitol.
Please contact your doctor or pharmacist if you are taking or have recently taken other medicines, including those obtained without a prescription. Do not forget to inform your doctor for the treatment with mannitol if you have been given any other medicine during treatment.
It is especially important to inform your doctor that you are treated with:
- ciclosporine;
- digoxin;
- lithium.

Taking Manitol with food and drinks

Mannitol is given as an infusion, thus it does not have any influence.

Pregnancy and breast-feeding

Category C.
Because of the absence of informations, its use during pregnancy and breast-feeding should be avoided.
Ask for the advice of the pharmacist or of the doctor before taking this drug.

Driving and using machines

No data.

3. HOW TO TAKE MANITOL

Administration route: intravenous infusion.
The dose is 1 - 2 g (5 - 10 ml of solution 20%) / kg of body weight; initially a test dose of 200 mg / kg is used by slow intravenous injection. In cerebral oedemas, it is provided a dose of 1 g / kg of body weight, as a 20 % solution.

If you take more Manitol than you should

If you take more Manitol than you should, or if the children have taken this medicine incorrectly, please contact your doctor or call the hospital or emergency to get an opinion for the risk and an advice for the actions to be taken.

4. POSSIBLE SIDE EFFECTS

Like all other medicines, Manitol may cause side effects, although not everybody manifests them.
The side effects that may happen are: hypersensitivity reactions, nausea, vomiting, headache, dizziness, tachycardia, chest pain, hyponatremia, hypernatremia, hypokalemia, cold sensation, urine retention, dehydration, blurred vision, convulsions, dry mouth, thirst, rhinitis, urticaria, pulmonary oedema, hypotension or hypertension, cramps, skin necrosis, thrombophlebitis, fluid and electrolyte imbalances, osmotic focal nephrosis.
Acidosis may appear during the administration of high doses.
Very rarely, congestive heart failure and acute renal failure may appear.

5. HOW TO STORE MANITOL

Keep out of the reach and sight of children!
Do not use Manitol after the expiry date, which is stated on the package!
Do not store above 25°C!
Store in the original packaging to protect it from light and humidity!
The solution may crystallise during storage, especially at low temperatures; crystals should be dissolved by warming the bottles or plastic bags before use.

6. FURTHER INFORMATION

What Manitol contains

The active substance is mannitol.
Each glass bottle or plastic bag 250 ml contains 50 g mannitol.
Each plastic bag 500 ml contains 100 g mannitol.
The other excipient is: water for injection.

Content of the pack

Glass bottle or plastic bag 250 ml.
Plastic bag 500 ml.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA Sh.a.
Rruga "Myslym Keta"
Tel.: 00 355 4 23 89 602
Tirana - ALBANIA

This leaflet was last revised in April 2012.

SPECIFICATION

CROPING AREA 12 x 19 cm

PAY ATENTION, all the layers are visible.
If you have to print this document please check or uncheck the specific layers.