PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

MANNITOL 20 % FRESENIUS

Solution for infusion.

Each 500 ml solution contains 100 g mannitol.

Contains sugar (mannitol).

Osmolarity: 1 098 mOsm/l

pH (approx.) 6.

Read all of this leaflet carefully before you are given MANNITOL 20 % FRESENIUS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

1. What MANNITOL 20 % FRESENIUS is and what it is used for

The active ingredient, mannitol, belongs to a group of medicines called osmotic diuretics.

MANNITOL 20 % FRESENIUS works in the kidneys by enhancing the excretion of sodium, potassium and chloride salts into the urine. These salts draw excess water from the blood into the urine.

MANNITOL 20 % FRESENIUS may be used to:

- maintain healthy functioning of kidneys
- determine if you have acute oliguria (the production of abnormally small amounts of urine)
- assist in the urinary excretion of toxic substances
- reduce pressure in the brain due to too much fluid retention (cerebral oedema) and in the eyes (intra-ocular oedema), and
- increase the concentration on the outside of the cells, which in turn may decrease cellular swelling and improve blood flow to the kidneys.

2. What you need to know before you are given MANNITOL 20 % FRESENIUS

You should not be given MANNITOL 20 % FRESENIUS if you:

- have established anuria (inability to produce urine), oliguria (reduced urine production) or azotaemia (kidney disease)

- have swelling and congested lungs (fluid accumulates in the lungs, see section 4)
- have bleeding in the brain, except during craniotomy (the surgical removal of part of the bone from the skull to expose the brain)
- have abnormal weakness of extremely thin blood vessels
- have dehydration (excessive loss of body water)
- have kidney failure, with no response to a test dose of MANNITOL 20 % FRESENIUS
- have congestive heart failure (heart problems which can cause shortness of breath or ankle swelling)
- also receive whole blood through the same infusion equipment before, while or after you receive blood.
- Pre-existing plasma hyperosmolarity, a condition in which the blood has high concentrations of salt, sugar and other substances.
- Disturbance of the blood-brain barrier (the network of blood vessels and tissue that helps keep harmful substances from reaching the brain).

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection if:

- you are hypersensitive (allergic) to mannitol
- you have heart, lung and kidney problems (see “You should not be given MANNITOL 20 % FRESENIUS if you")
- you have kidney dysfunction, heart failure or lung congestion (fluid accumulates in the lungs) that is worsening
- you are dehydrated causing high levels of salt and an increase in red blood cells in your blood
- you recently had an operation

- you have excessive fluid intake due to a mental condition (known as psychogenic polydipsia)
- you have high or low levels of potassium in the blood
- you have an acid-base imbalance in the body
- you have a fever (increased body temperature).

The risk for developing low levels of salt in the blood (hyponatraemia) is increased in children, women and elderly people.

The risk for developing damage or diseases that affects the brain (encephalopathy) due to low levels of salt in the blood (hyponatraemia) is increased in children, women and patients with low oxygen levels in the blood (hypoxaemia) and diseases of the nervous system.

Other medicines and MANNITOL 20 % FRESENIUS

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your healthcare provider if you are taking any of the following medicines, as they may interact with MANNITOL 20 % FRESENIUS:

- Water tablets (diuretics) used for swelling.
- A medicine used to stabilise your mood known as lithium.
- Antibiotics used to treat infections (such as aminoglycosides).
- A medicine used to suppress your immune system known as ciclosporin.
- Heart medicines (such as digoxin).
- Blood thinning medicines used to keep your blood from clotting.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before you are given MANNITOL 20 % FRESENIUS.

Driving and using machines

Your doctor will decide when to release you from hospital. MANNITOL 20 % FRESENIUS should not affect your ability to drive and use machines. You should however ask your doctor if you are fit enough after the procedure to drive a vehicle or handle machines.

MANNITOL 20 % FRESENIUS contains mannitol

MANNITOL 20 % FRESENIUS contains mannitol and may have a laxative effect.

3. How you will be given MANNITOL 20 % FRESENIUS

Do not share medicines prescribed for you with any other person.

You will not be expected to give MANNITOL 20 % FRESENIUS to yourself. MANNITOL 20 % FRESENIUS will be administered to you in the hospital, by a doctor or professional healthcare provider.

MANNITOL 20 % FRESENIUS will be infused (dripped) into a large vein. Your doctor will use a filter type administration set for large volumes.

- Your doctor will tell you how long your treatment with MANNITOL 20 % FRESENIUS will last. If you have the impression that MANNITOL 20 % FRESENIUS is too strong or too weak, tell your doctor or pharmacist.

- The usual dose to increase output of urine is 50 to 200 g over a 24 hour period of infusion. Your doctor will adjust your dose according to the quantity of urine you produce.

Your doctor will use different doses and infusion rates for different types of disorders.

If you receive more MANNITOL 20 % FRESENIUS than you should

Since a healthcare provider will administer this medicine, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you missed a dose of MANNITOL 20 % FRESENIUS

Since a healthcare provider will administer MANNITOL 20 % FRESENIUS, it is unlikely that a dose will be missed.

4. Possible side effects

MANNITOL 20 % FRESENIUS can have side effects.

Not all side effects reported for MANNITOL 20 % FRESENIUS are included in this leaflet. Should your general health worsen or you experience any untoward effects while receiving MANNITOL 20 % FRESENIUS, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop administration of MANNITOL 20 % FRESENIUS immediately:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.

- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to MANNITOL 20 % FRESENIUS. You may need urgent medical attention.

Tell your doctor immediately if the following happens:

- If you have difficulty breathing and coughing, as you may have congested lungs (fluid accumulates in the lungs).
- If you have severe headache, nausea and vomiting, which may be signs of increased pressure in the brain.
- Changes in the way your heart beats, for example if your heart beats very fast, irregular, slower than usual or if you can feel your heart beating (palpitations) and if you have angina-like chest pains.
- You produce more or less urine than is normal for you, or if there is traces of blood in your urine.

Tell your doctor if you notice any of the following:

Side effects with unknown frequency

- Fluid and electrolyte imbalance and acidosis (increased acidity in the blood and body tissues). Signs may be dehydration of tissues (excessive loss of body water), rapid breathing, muscle spasms, twitching, convulsions, irregular heartbeat, blood pressure changes, nausea (feeling sick), dry mouth or throat.
- Acute water toxicity if your renal flow is not adequate. Signs may be headache, changes in behaviour, confusion, irritability and drowsiness, shortness of breath and heart failure.
- Reactions at the area of injection: pain, redness, necrosis (dead skin) and thrombophlebitis (swelling and inflammation of a vein caused by a blood clot).
- Dizziness, blurred vision.

- Runny nose, sneezing.
- Dry mouth, thirst, nausea and vomiting.
- Arm pain and cramps.
- Chills and fever.
- Weakness, tiredness and feeling unwell.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of MANNITOL 20 % FRESENIUS.

Healthcare providers are asked to report any suspected adverse drug reactions to the Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicine's regulatory authority in the country where the product is marketed.

5. How to store MANNITOL 20 % FRESENIUS

- PVC bags and Kabipac bottles: store at or below 25 °C.
- **free***flex*® bags: store at or below 30 °C.
- Store all medicines out of reach of children.
- Do not use after the expiry date stated on the bag.

- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What MANNITOL 20 % FRESENIUS contains

Each 500 ml solution contains 100 g mannitol.

The other ingredients are hydrochloric acid (for pH-adjustment), sodium hydroxide (for pH-adjustment) and water for injection.

What MANNITOL 20 % FRESENIUS looks like and contents of the pack

A clear colourless or almost colourless solution. Crystals might be present which will dissolve on warming to 37 °C.

500 ml flexible PVC/**free***flex*® bags or 500 ml or 1 000 ml polyethylene bottles (Kabipac).

Pack sizes:

1, 18 or 20 PVC/**free***flex*® bags or Kabipac bottles are packed in a corrugated cardboard shipper box.

Not all pack sizes may be marketed.

Holder of Certificate of Registration and Manufacturer

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