

APPROVED PATIENT INFORMATION LEAFLET
MANNITOL 5 % IRRIGATION SOLUTION FRESENIUS

SCHEDULING STATUS

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MANNITOL 5 % IRRIGATION SOLUTION FRESENIUS

Solution for irrigation.

Each 1 000 mL-solution contains 50 g mannitol.

Contains sugar (mannitol).

Osmolarity: 274 mOsmol/L

pH (approx.) 6.

Read all of this leaflet carefully before you are irrigated with MANNITOL 5 % IRRIGATION SOLUTION 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 5 % IRRIGATION SOLUTION FRESENIUS is and what it is used for
2. What you need to know before you are irrigated with MANNITOL 5 % IRRIGATION SOLUTION FRESENIUS
3. How MANNITOL 5 % IRRIGATION SOLUTION FRESENIUS should be used
4. Possible side effects
5. How to store MANNITOL 5 % IRRIGATION SOLUTION FRESENIUS

6. Contents of the pack and other information.

1. What MANNITOL 5 % IRRIGATION SOLUTION FRESENIUS is and what it is used for

MANNITOL 5 % IRRIGATION SOLUTION FRESENIUS is used for flushing out the bladder during a urological procedure to remove portions of the prostate gland. This helps to limit the breakdown of red blood cells, known as haemolysis.

2. What you need to know before you are irrigated with MANNITOL 5 % IRRIGATION SOLUTION FRESENIUS

You should not be irrigated with MANNITOL 5 % IRRIGATION SOLUTION FRESENIUS if you:

- Are hypersensitive (allergic) to mannitol or any of the other ingredients of MANNITOL 5 % IRRIGATION SOLUTION FRESENIUS (listed in section 6).
- Have fluid accumulation in the lungs, causing shortness of breath, difficulty in breathing and wheezing (known as pulmonary congestion or oedema).
- Have bleeding within the skull (known as intracranial bleeding) caused by damaged blood vessels and head injuries.
- Have heart or kidney failure.

Warnings and precautions

Tell your doctor or healthcare professional before being irrigated with MANNITOL 5 % IRRIGATION SOLUTION FRESENIUS if you have heart, kidney or lung problems.

Other medicines and MANNITOL 5 % IRRIGATION SOLUTION FRESENIUS

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

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 irrigated with MANNITOL 5 % IRRIGATION SOLUTION FRESENIUS.

Driving and using machines

Your doctor will decide when to release you from hospital. MANNITOL 5 % IRRIGATION SOLUTION 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.

3. How MANNITOL 5 % IRRIGATION SOLUTION FRESENIUS should be used

For irrigation only and NOT for injection.

You will not be expected to use MANNITOL 5 % IRRIGATION SOLUTION FRESENIUS on yourself; it will be administered by a person who is qualified to do so.

No specific dose is prescribed, the doctor performing the procedure will use as much MANNITOL 5 % IRRIGATION SOLUTION FRESENIUS as is necessary for flushing out your bladder in the theatre.

If you receive more MANNITOL 5 % IRRIGATION SOLUTION FRESENIUS than you should

Since a healthcare professional 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 5 % IRRIGATION SOLUTION FRESENIUS

Since a healthcare provider will administer MANNITOL 5 % IRRIGATION SOLUTION FRESENIUS, it is unlikely that a dose will be missed.

4. Possible side effects

MANNITOL 5 % IRRIGATION SOLUTION FRESENIUS can have side effects.

Not all side effects reported for MANNITOL 5 % IRRIGATION SOLUTION FRESENIUS are included in this leaflet. Should your general health worsen, or you experience any untoward effects while receiving MANNITOL 5 % IRRIGATION SOLUTION FRESENIUS, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop irrigation with MANNITOL 5 % IRRIGATION SOLUTION 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 5 % IRRIGATION SOLUTION FRESENIUS. You may need urgent medical attention.

Tell your doctor if you experience any of the following reactions after receiving MANNITOL 5 % IRRIGATION SOLUTION FRESENIUS:

Frequent side effects:

- Fluid and electrolyte imbalance including circulatory overload. A fluid imbalance may occur when you lose more water or fluid than your body can take in or when you take in more water or fluid than your body is able to get rid of.

Applicant: FRESENIUS KABI MANUFACTURING SA (Pty) Ltd.

Product Proprietary Name: MANNITOL 5 % FRESENIUS

Approval date: 26 January 2026



- Tissue dehydration (loss of water).

Side effects with unknown frequency:

- Swelling and skin necrosis (skin dies and falls off).

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **MANNITOL 5 % IRRIGATION SOLUTION FRESENIUS**.

Patients are asked to report any suspected adverse drug reactions to their healthcare provider or 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 5 % IRRIGATION SOLUTION FRESENIUS

- Store at or below 25 °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 5 % IRRIGATION SOLUTION FRESENIUS contains

Each 1 000 mL solution contains 50 g mannitol.

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The other ingredient is water for injection.

What MANNITOL 5 % IRRIGATION SOLUTION FRESENIUS looks like and contents of the pack

MANNITOL 5 % IRRIGATION SOLUTION FRESENIUS is a clear colourless or almost colourless solution. Crystals might be present which will dissolve on warming to 37 °C.

3 000 mL PVC bags.

Pack size: 4 bags are packed into a corrugated cardboard shipper/box.

Holder of Certificate of Registration and Manufacturer

Fresenius Kabi Manufacturing SA (Pty) Ltd

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Korsten, 6020

Gqeberha

South Africa

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31/34/0163

Access to the corresponding Professional Information

The professional information will be printed and packaged with the product.