APPROVED PROFESSIONAL INFORMATION

MANNITOL 5 % IRRIGATION SOLUTION FRESENIUS

SCHEDULING STATUS

S1

1. NAME OF THE MEDICINE

MANNITOL 5 % IRRIGATION SOLUTION FRESENIUS

Solution for irrigation.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 000 mL-solution contains 50 g of mannitol.

Contains sugar (mannitol).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for irrigation.

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

Osmolarity: 274 mOsmol/L

pH (approx.): 6.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Bladder irrigation during transurethral resection of the prostate in order to reduce haemolysis.

4.2 Posology and method of administration

As required for irrigation. Not for intravenous administration. Not to be mixed with other products.

If necessary, warm before use to dissolve crystals. Do not heat in excess of 66 °C.

Use administration set with a filter. For single use only. Discard unused portion.

The use of aseptic technique is essential when irrigating solutions are used for the irrigation of body cavities, wound and urethral catheters. Do not use unless solution is clear, and the container is undamaged with the seal intact.

Special populations:

Cardiopulmonary and renal dysfunction

Use with caution in patients with severe cardiopulmonary or renal dysfunction. Since systemic absorption of large amounts of solution is possible in patients suffering from these conditions, cardiopulmonary or renal dysfunction may be altered substantially (see section 4.3).

Paediatric population

The safety and efficacy in children have not been established.

4.3 Contraindications

MANNITOL 5 % IRRIGATION SOLUTION FRESENIUS is contraindicated in patients with:

- hypersensitivity to mannitol or to any of the excipients listed in section 6.1
- pulmonary congestion or oedema
- intracranial bleeding (except during craniotomy)
- heart failure (in patients with diminished cardiac reserve, expansion of the extracellular fluid may lead to fulminating heart failure)
- metabolic oedema with abnormal capillary fragility, and
- renal failure.
- MANNITOL 5 % IRRIGATION SOLUTION FRESENIUS should not be administered with whole blood.

Irrigation solutions should generally not be used in conditions in which systemic absorption may result. MANNITOL 5 % IRRIGATION SOLUTION FRESENIUS should be used with caution in patients with severe cardiopulmonary or renal dysfunction since systemic absorption of large amounts of solution may substantially alter cardiopulmonary or renal dysfunction.

4.4 Special warnings and precautions for use

All patients given MANNITOL 5 % IRRIGATION SOLUTION FRESENIUS should be carefully observed for signs of fluid and electrolyte imbalance and renal function should be monitored. Displaced catheters can lead to irritation or infiltration of unintended structures or cavities.

Irrigating fluids used during transurethral prostatectomy have been demonstrated to enter the systemic circulation in relatively large volumes. Any irrigation solution must be regarded as a systemic medicine.

CNS toxicity:

CNS toxicity manifested by, for example confusion, lethargy, coma, has been reported in patients treated with mannitol, in particular in the presence of impaired renal function. Fatal outcomes have been reported.

CNS toxicity may result from:

- high serum mannitol concentrations
- serum hyperosmolarity resulting in intracellular dehydration within the CNS
- hyponatraemia or other disturbances of electrolyte and acid/base balance secondary to mannitol administration.

At high concentrations, mannitol may cross the blood brain barrier and interfere with the ability of the brain to maintain the pH of the cerebrospinal fluid especially in the presence of acidosis.

In patients with pre-existing compromised blood brain barrier, the risk of increasing cerebral oedema (general or focal) associated with repeated or continued use of mannitol must be individually weighed against the expected benefits.

A rebound increase of intracranial pressure may occur several hours after the use of mannitol.

Patients with compromised blood brain barrier are at increased risk.

Absorption of large amounts of fluids containing mannitol and the resultant osmotic diuresis may significantly affect cardiopulmonary and renal dynamics.

From a microbiological point of view, the product should be used immediately. Any unused portion should be discarded, due to the risk of bacterial growth or pyrogen formation.

4.5 Interaction with other medicines and other forms of interaction

MANNITOL 5 % IRRIGATION SOLUTION FRESENIUS should not be administered with whole blood.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

There is no information of the effects of MANNITOL 5 % IRRIGATION SOLUTION FRESENIUS on the ability to operate a vehicle or other heavy machinery.

4.8 Undesirable effects

Metabolism and nutrition disorders

Frequent:

Fluid and electrolyte imbalance, circulatory overload and acidosis. The shift of fluid from the intracellular to extracellular compartment can cause tissue dehydration.

Skin and subcutaneous tissue disorders

Frequency unknown:

Hypersensitivity reactions, oedema and skin necrosis.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of MANNITOL 5 % IRRIGATION SOLUTION FRESENIUS is important. It allows continued monitoring of the benefit/risk balance of MANNITOL 5 % IRRIGATION SOLUTION FRESENIUS. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

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.

4.9 Overdose

See section 4.8. If adverse effects, overhydration, or solute overload occurs with the irrigation solution, it should be discontinued, the patient closely evaluated, and appropriate corrective therapy instituted if necessary.

Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 34 Other.

Pharmacotherapeutic group: Blood substitutes and perfusion solutions, irrigation solutions, other irrigating solutions.

ATC code: B05CX04.

Mannitol is an osmotic agent.

5.2 Pharmacokinetic properties

When administered intravenously, mannitol is eliminated largely unmetabolised through the glomeruli. Only 10 % is reabsorbed back from the kidney tubule. The elimination half-life in adults is approximately 2 hours, longer where renal failure is present. 80 % of an intravenous dose is excreted unchanged within 3 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injection.

6.2 Incompatibilities

In the absence of compatibility studies, MANNITOL 5 % IRRIGATION SOLUTION FRESENIUS may not be mixed with other products.

MANNITOL 5 % IRRIGATION SOLUTION FRESENIUS should not be administered with whole blood.

6.3 Shelf life

18 months.

6.4 Special precautions for storage

Store at or below 25 °C.

Do not heat in excess of 66 °C (see section 4.2).

6.5 Nature and contents of container

3 000 mL PVC bags.

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

6.6 Special precautions for disposal and other handling

Use administration set with a filter. For single use only. Discard unused portion.

The use of aseptic technique is essential when irrigating solutions are used for the irrigation of body cavities, wound and urethral catheters. Do not use unless solution is clear, and the container is undamaged with the seal intact.

Check for minute leaks by squeezing the bag.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Fresenius Kabi Manufacturing SA (Pty) Ltd

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Korsten, 6020

Gqeberha

South Africa

Telephone number: +27 (0)86 020 3900

8. REGISTRATION NUMBER

31/34/0163

9. DATE OF FIRST AUTHORISATION

18 April 1997

10. DATE OF REVISION OF THE TEXT

26 January 2026