

APPROVED PROFESSIONAL INFORMATION

SCHEDULING STATUS

S1

1. NAME OF THE MEDICINE

WATER FOR IRRIGATION FRESENIUS Solution for irrigation.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each container of solution for irrigation contains water for injection.

Sugar free.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Clear, odourless, colourless liquid.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Wound irrigation.

4.2 Posology and method of administration

Posology

As required for irrigation.

For single use only.

Discard unused portion.

4.3 Contraindications

None

4.4 Special warnings and precautions for use

WATER FOR IRRIGATION FRESENIUS must not be used for intravenous infusion.

WATER FOR IRRIGATION FRESENIUS is hypotonic. It may cause haemolysis of red blood cells.

4.5 Interaction with other medicines and other forms of interaction

Interactions between WATER FOR IRRIGATION FRESENIUS and other medicines are not known.

4.6 Fertility, pregnancy, and lactation

Pregnancy

Generally, WATER FOR IRRIGATION FRESENIUS can be used during pregnancy.

Breastfeeding

WATER FOR IRRIGATION FRESENIUS can be used during breastfeeding.

Fertility

No data available.

4.7 Effects on ability to drive and use machines

WATER FOR IRRIGATION FRESENIUS has no influence on the ability to drive and use machines.

4.8 Undesirable effects

None known if used according to the instructions given.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are requested to report any suspected adverse drug 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

There is a possibility of fluid absorption. If this occurs in excess, hypervolaemia and renal failure may result. Treat symptomatically paying particular attention to restoring the electrolyte balance.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 34 Other

ATC code: V07AB

Pharmacotherapeutic group: Solvents and diluting agents, including irrigating solutions

Water for Irrigation is a liquid for irrigation of wounds.

5.2 Pharmacokinetic properties

None

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Inactive ingredients: None.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months

6.4 Special precautions for storage

freeflex® bags: Store at or below 30 °C.

PVC Bags, Polyethylene Bottle (KabiPac) and Polypropylene Bottle: Store at or below 25 °C.

6.5 Nature and contents of container

500 ml or 1 000 ml PVC or **freeflex®** bags

1 000 ml Polyethylene bottles

Not all pack sizes are marketed.

6.6 Special precautions for disposal

No special requirements for disposal.

Only to be used if solution is clear, colourless and the container and its closure are undamaged.

The containers are for single use only. After use, discard container and any remaining contents.

Use the liquid immediately after opening of the container.

Applicant: **FRESENIUS KABI Manufacturing SA (Pty) Ltd.**
Product Proprietary Name: WATER FOR IRRIGATION FRESENIUS
Approval date: 25 June 2025



7. HOLDER OF CERTIFICATE OF REGISTRATION

Fresenius Kabi Manufacturing SA (Pty) Ltd

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Korsten 6020

Gqeberha

South Africa

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8. REGISTRATION NUMBER

L/34/338

9. DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION

Approved on: 25 October 1999

10. DATE OF REVISION OF THE TEXT

25 June 2025

Namibia:	NS1	90/34/00426
Zimbabwe:	31 Miscellaneous, 2025/31/7029, PP	