

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

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WATER FOR IRRIGATION FRESENIUS

Water for injection

Sugar free

Read all of this leaflet carefully because it contains important information for you

- Keep this leaflet. You may need to read it again.
- Do not share WATER FOR IRRIGATION FRESENIUS with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What WATER FOR IRRIGATION FRESENIUS is and what it is used for
2. What you need to know before you use WATER FOR IRRIGATION FRESENIUS
3. How to use WATER FOR IRRIGATION FRESENIUS
4. Possible side effects
5. How to store WATER FOR IRRIGATION FRESENIUS
6. Contents of the pack and other information

1. What WATER FOR IRRIGATION FRESENIUS is and what it is used for

Wound irrigation.

2. What you need to know before you use WATER FOR IRRIGATION FRESENIUS

There are no known contraindications for WATER FOR IRRIGATION FRESENIUS.

Applicant: FRESenius KABI Manufacturing SA (Pty) Ltd.

Product Proprietary Name: WATER FOR IRRIGATION FRESenius

Approval date: 25 June 2025



Warnings and precautions

Take special care with WATER FOR IRRIGATION FRESenius

WATER FOR IRRIGATION FRESenius must not be used for intravenous administration.

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

Other medicines and WATER FOR IRRIGATION FRESenius

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

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

Pregnancy, breastfeeding and fertility

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 using this medicine.

Pregnancy

Generally, water for irrigation can be used during pregnancy.

Breastfeeding

Water for irrigation can be used during breastfeeding.

Fertility

There are no data on the effect of water for irrigation on fertility.

Driving and using machines

WATER FOR IRRIGATION FRESenius has no influence on the ability to drive and use

machines.

3. How to use WATER FOR IRRIGATION FREENIUS

Your doctor will tell you how long your treatment with WATER FOR IRRIGATION FREENIUS will last.

WATER FOR IRRIGATION FREENIUS is used as required for irrigation only.

It is not used for injection.

For single use only.

Discard any unused portion.

If you use more WATER FOR IRRIGATION FREENIUS than you should

As this medicine will be given to you whilst you are in hospital it is unlikely that you will be given too little or too much, however tell your doctor or pharmacist if you have any concerns.

There is a possibility of fluid absorption, if this occurs it could lead to excess fluid overload (hypervolaemia) and renal failure may result from this. Treat symptomatically paying particular attention to restoring the electrolyte balance.

Since a healthcare provider will administer WATER FOR IRRIGATION FREENIUS, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If a doctor is not available, contact the nearest hospital or poison centre.

4. Possible side effects

WATER FOR IRRIGATION FREENIUS can have side effects.

Not all side effects reported for WATER FOR IRRIGATION FREENIUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects

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while using WATER FOR IRRIGATION FRESENIUS, please consult your healthcare provider for advice.

There are no known side effects if the instructions are followed correctly.

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 your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of WATER FOR IRRIGATION FRESENIUS.

Patients 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 WATER FOR IRRIGATION FRESENIUS

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

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

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

Keep in original packaging until required for use.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What WATER FOR IRRIGATION FRESENIUS contains

Each container of solution for irrigation contains water for injection.

Inactive ingredients: None

What WATER FOR IRRIGATION FRESENIUS looks like and contents of the pack

Clear, odourless, colourless liquid.

Holder of Certificate of Registration

Fresenius Kabi Manufacturing SA (Pty) Ltd

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South Africa

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This leaflet was last revised in

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Registration Number

L/34/338

Access to the corresponding Professional Information

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

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Namibia:

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Zimbabwe: 31 Miscellaneous, 2025/31/7029, PP