

Applicant: FRESENIUS KABI SOUTH AFRICA (Pty) Ltd.

Product Proprietary Name: WATER FOR INJECTION (FLEXIVIAL) FRESENIUS

Dosage form and strength: 1 mL water for injection per 1 mL solution

Approval date: 29 April 2025



APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S1

WATER FOR INJECTION (FLEXIVIAL) FRESENIUS

Diluent for injection

Water for injection

Sugar free

Read all of this leaflet carefully before you start using WATER FOR INJECTION (FLEXIVIAL) 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 WATER FOR INJECTION (FLEXIVIAL) FRESENIUS is and what it is used for
2. What you need to know before you are given WATER FOR INJECTION (FLEXIVIAL) FRESENIUS
3. How to use WATER FOR INJECTION (FLEXIVIAL) FRESENIUS
4. Possible side effects
5. How to store WATER FOR INJECTION (FLEXIVIAL) FRESENIUS
6. Contents of the pack and other information

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1. What WATER FOR INJECTION (FLEXIVIAL) FRESENIUS is and what it is used for

WATER FOR INJECTION (FLEXIVIAL) FRESENIUS is pure, sterile water.

It is used to dissolve or dilute medicines before use. For example, medicines that are given by:

- injection (given using a needle, for example into your vein)
- infusion (slow injection) into a vein, also called a 'drip'.

2. What you need to know before you are given WATER FOR INJECTION (FLEXIVIAL) FRESENIUS

Do not receive WATER FOR INJECTION (FLEXIVIAL) FRESENIUS:

- as an injection or infusion on its own.

WATER FOR INJECTION (FLEXIVIAL) FRESENIUS will always be mixed with one or more medicines by a healthcare professional before you receive it.

You should read the Patient Information Leaflet of your medicine or medicines that are being mixed with WATER FOR INJECTION (FLEXIVIAL) FRESENIUS. This will tell you whether or not you can receive the solution.

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Warnings and precautions

Take special care with WATER FOR INJECTION (FLEXIVIAL) FRESENIUS.

Talk to your doctor or pharmacist before receiving WATER FOR INJECTION (FLEXIVIAL) FRESENIUS. Water for injection should not be used on its own.

Before you receive WATER FOR INJECTION (FLEXIVIAL) FRESENIUS it will always be mixed with one or more medicines. Your healthcare provider will make sure that the mixture is roughly the same consistency as your blood (isotonic). Depending on the type of medicine you are given, this will mean that:

- the medicine needs to be diluted with WATER FOR INJECTION (FLEXIVIAL) FRESENIUS
- another substance needs to be added to your mixture of WATER FOR INJECTION (FLEXIVIAL) FRESENIUS and medicine before use.

You will be more likely to suffer haemolysis (breakdown of red blood cells) if you are given large volumes of hypotonic solutions of WATER FOR INJECTION (FLEXIVIAL) FRESENIUS (solutions that are not as concentrated as your blood). To help preventing this, your doctor will take a blood sample to monitor the balance of the chemicals in your blood (the ionic balance).

Other medicines and WATER FOR INJECTION (FLEXIVIAL) FRESENIUS

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Always tell your healthcare provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

The medicines you are using may interact with the medicine mixed with WATER FOR INJECTION (FLEXIVIAL) FRESENIUS. Your doctor will check up on possible interactions.

WATER FOR INJECTION (FLEXIVIAL) FRESENIUS with food or drink

You should ask your doctor about what you can eat or drink.

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 the medicine dissolved in WATER FOR INJECTION (FLEXIVIAL) FRESENIUS.

Driving and using machines

Ask your doctor for advice about the effect of the medicines that is going to be dissolved or diluted with WATER FOR INJECTION (FLEXIVIAL) FRESENIUS.

3. How to use WATER FOR INJECTION (FLEXIVIAL) FRESENIUS

You will not be expected to give yourself WATER FOR INJECTION (FLEXIVIAL) FRESENIUS. It will be mixed with your medicine and given to you by a person who is qualified to do so.

Your doctor or nurse will use the correct amount of WATER FOR INJECTION (FLEXIVIAL) FRESENIUS to dissolve or dilute the medicine

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that you are receiving as an injection, or as an infusion (a drip) into your veins. (**Handling instructions** are provided in the Professional Information for the plastic ampoules).

Your doctor will decide on the dose of the medicine that you should receive and how long you will need to receive it.

If you use more WATER FOR INJECTION (FLEXIVIAL) FRESENIUS than you should

Since a healthcare provider will administer WATER FOR INJECTION (FLEXIVIAL) FRESENIUS with the solution of the medicine it has been mixed with, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use WATER FOR INJECTION (FLEXIVIAL) FRESENIUS

Since a healthcare provider will administer WATER FOR INJECTION (FLEXIVIAL) FRESENIUS with the solution of the medicine it has been mixed with, it is unlikely that a dose will be missed.

4. Possible side effects

WATER FOR INJECTION (FLEXIVIAL) FRESENIUS can have side effects.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using the solution of the medicine mixed with WATER FOR INJECTION (FLEXIVIAL) FRESENIUS, please consult your healthcare provider for advice.

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If given on its own, intravenous WATER FOR INJECTION (FLEXIVIAL) FRESENIUS may cause damage to the red blood cells (haemolysis).

The medicine added to WATER FOR INJECTION (FLEXIVIAL) FRESENIUS may also cause side effects. These side effects will depend on the medicine added. You should read the Patient Information Leaflet of the added medicine for a list of possible symptoms.

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 (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of WATER FOR INJECTION (FLEXIVIAL) FRESENIUS.

Patients are asked to report any suspected adverse drug reactions to their healthcare provider or Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicines regulatory authority in the country where the product is marketed.

5. How to store WATER FOR INJECTION (FLEXIVIAL) FRESENIUS

Store all medicines out of reach of children.

- Store at or below 25 °C. Keep the ampoules in the outer carton.
- Do not use if the ampoule is damaged or if the contents are discoloured.
- If only part is used, discard the remaining solution.

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- For single use only.
- Do not use the medicine after the expiry date printed on the carton and bottle.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What WATER FOR INJECTION (FLEXIVIAL) FRESENIUS contains

The active substance is water for injection. Each presentation contains 100 % sterile water for injection.

The other ingredients are: None

What WATER FOR INJECTION (FLEXIVIAL) FRESENIUS looks like and contents of the pack

A clear colourless solution, free from visible particles.

Ampoules of 5 mL, 10 mL or 20 mL low density polyethylene.

Packs of 10, 20, 50 and 100 plastic ampoules.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

FRESENIUS KABI SOUTH AFRICA (PTY) LTD

Stand 7, Growthpoint Business Park

162 Tonetti Street

Halfway House extension 7

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Gauteng

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Telephone number: (011) 545 0000

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Registration number

L/34/155

Access to the corresponding Professional Information

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