APPROVED PROFESSIONAL INFORMATION

SCHEDULING STATUS

S1

1. NAME OF THE MEDICINE

WATER FOR INJECTION (FLEXIVIAL) FRESENIUS Diluent for injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 mL of solution contains 1 mL water for injection.

Each 5,0 mL, 10,0 mL or 20,0 mL ampoule contains 5 mL, 10 mL or 20 mL water for injection.

pH between 4,5 and 7,0.

Excipients: None - see section 6.1.

3. PHARMACEUTICAL FORM

Diluent for injection.

Clear, colourless, sterile water for injection

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For use as a solvent for parenteral products such as sterile solids that must be distributed dry because of limited stability of their solutions, or for dilution of concentrated solutions.

4.2 Posology and method of administration

Posology

According to the concentration of the active ingredient required.

Method of administration

Injection.

4.3 Contraindications

WATER FOR INJECTION (FLEXIVIAL) FRESENIUS must not be administered alone.

The contraindications related to the added medicine should be considered.

4.4 Special warnings and precautions for use

WATER FOR INJECTION (FLEXIVIAL) FRESENIUS is hypotonic and must not be administered alone (see section 4.3)

Do not use for intravenous injection unless adjusted to approximate isotonicity with a suitable solute.

When WATER FOR INJECTION (FLEXIVIAL) FRESENIUS is used as a diluent of hypertonic solutions, appropriate dilution should be applied to bring the solution close to isotonicity.

Haemolysis may occur following infusion of large volumes of hypotonic solutions using sterile water for injections as diluent.

When administering large volumes, the ionic balance should be regularly monitored.

4.5 Interaction with other medicines and other forms of interaction

Not applicable.

The possible clinical interactions between the different medicines to be dissolved should be considered.

4.6 Fertility, pregnancy and lactation

Not applicable.

The possible risks are determined by the nature of the added medicines.

4.7 Effects on ability to drive and use machines.

Not relevant.

4.8 Undesirable effects

Not be administered alone. WATER FOR INJECTION (FLEXIVIAL) FRESENIUS may cause haemolysis if administered alone.

The nature of the additive will determine the likelihood of any other undesirable effects.

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. Health care 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, either directly or via the national pharmacovigilance electronic reporting systems.

4.9 Overdose

Not applicable.

Haemolysis may occur following infusion of large volumes of hypotonic solutions using sterile water for injections as diluent.

Signs and symptoms of overdose are determined by the nature of the added medicine.

In the event of accidental overdose, the treatment should be discontinued, and the patient should be observed for the appropriate signs and symptoms related to the medicine administered.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 34 Other

Pharmacotherapeutic group: Solvent and diluting agents, incl. Irrigating solutions,

ATC code: V07AB

Water for injection is a solvent for injectable aqueous solutions. The pharmacodynamics will depend on the nature of the medicine added.

5.2 Pharmacokinetic properties

Pharmacokinetics will depend on the nature of the medicine added.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None

6.2 Incompatibilities

Additives may be incompatible. Those additives known to be incompatible should not be used.

Before adding medicines, verify

- They are soluble and stable in water at the pH of WATER FOR INJECTION (FLEXIVIAL) FRESENIUS.
- They are compatible with each other.

In the absence of compatibility studies, WATER FOR INJECTION (FLEXIVIAL) FRESENIUS must not be mixed with other medicines.

6.3 Shelf life

Ampoules containing 5 mL, 10 mL and 20 mL: 2 years.

Shelf life after first opening: immediate use.

6.4 Special precautions for storage

Store at or below 25 °C.

Keep the ampoule in the outer carton.

6.5 Nature and contents of the container

Low density polyethylene ampoules

5 mL, 10 mL or 20 mL ampoules

Package with 20 ampoules containing 5 mL

Package with 50 ampoules containing 5 mL

Package with 20 ampoules containing 10 mL

Package with 50 ampoules containing 10 mL

Package with 20 ampoules containing 20 mL

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Discard any unused portion after single use.

Use only if the solution is clear without visible particles and container undamaged.

Thorough and careful aseptic mixing of any additive is mandatory.

Make the infusion isotonic prior to parenteral administration.

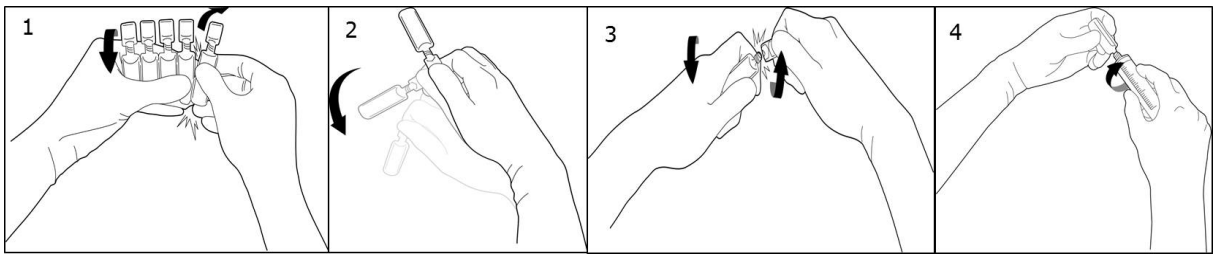
Solutions containing additives should be used immediately after preparation unless preparation has taken place in controlled and validated aseptic conditions.

The solution is for dilution and delivery of the therapeutic additives. The directions for use related to the added medicine will dictate the appropriate volumes, as well as the administration route.

Handling instructions:

To break off a single ampoule, twist one ampoule against the remaining ampoules of the pack without touching the head and neck of the ampoules (1). Shake the ampoule with one single movement as shown below in order to remove the liquid

kept in the cap (2). To open the ampoule, twist the ampoule body and the ampoule head in opposite directions until the neck breaks off (3). Connect the ampoule to the Luer-syringe or Luer-lock syringe as shown in figure (4).



Therefore, no needle is needed to extract the solution. Extract the liquid.

7. HOLDER OF CERTIFICATE OF REGISTRATION

FRESENIUS KABI SOUTH AFRICA (PTY) LTD

Stand 7, Growthpoint Business Park

162 Tonetti Street

Halfway House extension 7

Midrand

Gauteng

1685

Telephone number: (011) 545 0000

8. REGISTRATION NUMBER

L/34/155

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19 July 1979

10. DATE OF REVISION OF THE TEXT

29 April 2025