Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Water for injections, solvent for parenteral use

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Water for injections 1 g per 1 ml
pH between 4.5 and 7.0.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solvent for parenteral use.
Clear and colourless solution

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Sterile Water for injections is indicated to serve as a vehicle for dilution and reconstitution of suitable medicinal products for parenteral administration.

4.2 Posology and method of administration

Posology

The dosage administered will be dictated by the nature of the additive used. The administration rate will be dependent on the dose regimen of the prescribed drug.

Following suitable admixture of prescribed additives, the dosage is usually dependent upon the age, weight and clinical condition of the patients, as well as laboratory determinations.

Method of administration

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

4.3 Contraindications

Water for injections should not be administered alone.
The contraindications related to the added medicinal product should be considered.

4.4 Special warnings and precautions for use

Water for injections is hypotonic and should not be administered alone.
Do not use for intravenous injection unless adjusted to approximate isotonicity with a suitable solute.
When Water for injections 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.

The large volume presentations (500 and 1000 ml) are for use as a bulk source of diluent in pharmacy compounding. They are not for direct intravenous administration.

4.5 Interaction with other medicinal products and other forms of interaction

None known.
The possible clinical interactions between different medicinal products to be dissolved should be considered.

4.6 Fertility, pregnancy and lactation

The risk during use in pregnancy and in lactating women are determined by the nature of the added medicinal products.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Intravenous injections of Water for injections may cause haemolysis if Water for injections is administered alone.
The nature of the additive will determine the likelihood of any other undesirable effects.

Reporting of suspected adverse reactions
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Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail:medsafety@hpra.ie.

4.9 Overdose

Haemolysis may occur following infusion of large volumes of hypotonic solutions using sterile water for injections as diluent.
The signs and symptoms of overdose will also be related to the nature of the medicinal product being added. 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 medicinal product administrated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Solvent and diluting agents, incl. Irrigating solutions, ATC code: V07AB

Water for injections being only the vehicle for the administration of the added medicinal product, the pharmacodynamics will depend on the nature of the drug added.

5.2 Pharmacokinetic properties

Water for injections being only the vehicle for the administration of the added medicinal product, the pharmacokinetics will depend on the nature of the drug added.

5.3 Preclinical safety data

Water for injections being only the vehicle for the administration of the added medicinal product, the preclinical safety data for the solutions in use will depend on the nature of the drug 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 drugs, verify

- They are soluble and stable in water at the pH of Water for injections.
- They are compatible with each other

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

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

This medicinal product does not require any special storage conditions.
Keep the ampoule in the outer carton.

6.5 Nature and contents of container

Low density polyethylene (LDPE) 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

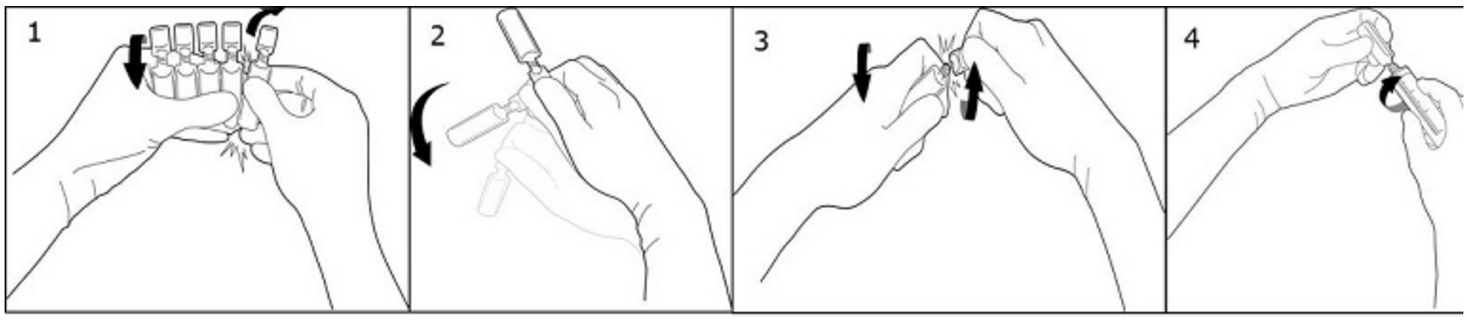
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Discard after single use. Discard any unused portion. Use only if the solution is clear without visible particles and container undamaged. Thorough and carefull 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.

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 MARKETING AUTHORISATION HOLDER

Fresenius Kabi Ltd
Cestrian Court
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8 MARKETING AUTHORISATION NUMBER

PA 0566/053/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7th August 2009
Date of last renewal: 13th March 2011

10 DATE OF REVISION OF THE TEXT

June 2015