

SUMMARY OF PRODUCT CHARACTERISTICS

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1 NAME OF THE MEDICINAL PRODUCT

Water for Injections B. Braun solvent for parenteral use

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

100 ml of solvent contain:

Water for injections 100 ml

3 PHARMACEUTICAL FORM

Solvent for parenteral use

Clear, colourless solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Preparation and dilution of parenteral preparations

4.2 Posology and method of administration

Posology

Water for Injection is used for dilution or dissolution of parenteral medicinal products. Dosage and duration of use depend on the instructions given for the medicinal product to be dissolved or diluted.

Paediatric population

The dosage has to be considered based on the instructions given for the medicinal product to be dissolved or diluted.

Method of administration

The method of administration depends on the instructions given for the medicinal product to be dissolved/diluted. The medicinal products should be reconstituted or diluted immediately before use.

4.3 Contraindications

There are no contraindications for water for injections as such.

4.4. Special warnings and precautions for use

Water for Injections must not be used alone for intravenous administration.

4.5 Interactions with other medicinal products and other forms of interaction

Interactions between water for injections and other medicinal products are not known.

4.6 Fertility, pregnancy and lactation

Pregnancy

Generally, water for injections can be used during pregnancy.

Breast-feeding

Water for injections can be used during breast-feeding.

Fertility

No data available.

4.7 Effects on ability to drive and use machines

Water for Injections B. Braun has no influence on the ability to drive and use machines.

4.8 Undesirable effects

None known if used according to the instructions given.

4.9 Overdose

Symptoms and treatment

Not applicable because this medicinal product is only for preparation and dilution of parenteral preparations.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Solvents and diluting agents, incl. irrigating solutions

ATC code: V07AB

5.2 Pharmacokinetic properties

None

5.3 Preclinical safety data

Non-clinical data on water for injection reveal no special hazard for humans.

Studies of toxicity to reproduction, genotoxicity or carcinogenic potential have not been performed, but based on the chemical properties of water and the fact that water is essential to life, pure water would not be expected to generate positive mutagenic or carcinogenic data.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Unopened

Polyethylene ampoules 5 ml: 24 months

Polyethylene ampoules 10 ml: 36 months

After first opening

Not applicable. See section 6.6.

After admixture of additives

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 °C, unless dilution has taken place in controlled and validated aseptic conditions.

6.4 Special precautions for storage

Do not store above 30 °C.

Storage conditions of ready-to-use preparations see section 6.3.

6.5 Nature and contents of container

Polyethylene ampoules,

contents: 5 ml, 10 ml

pack sizes: 20 x 5 ml, 20 x 10 ml, 100 x 5 ml, 100 x 10 ml

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

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.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

To be completed nationally

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

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