Effective

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Water for Injections BP, solvent for parenteral use

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

100 ml of solventcontains:
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

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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 Interaction with other medicinal products and other forms of interaction

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

4.6 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 has no influence on the ability to drive and use machines

4.8 Undesirable effects

None known if used according to the instructions given.

Reporting of 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 The Yellow Card Scheme: Website: www.mhra.gov.uk/yellowcard

4.9 Overdose

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

5 PHARMACOLOGICAL PROPERTIES

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5.1 Pharmacodynamic properties

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

-ATC code: VO7AB

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 containers 36 months
Polyethylene ampoule 2 ml: 24 months
Polyethylene ampoules 5 ml, 10 ml, 20 ml: 30 months
Polypropylene ampoules 10 ml, 20 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 – 8 ºC, unless dilution has taken place in controlled and validated aseptic conditions.

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6.4 Special precautions for storage

Product in plastic ampoules: Do not store above 25 °C.
Product in polyethylene containers: This medicinal product does not require any special storage conditions.
For storage conditions of ready-to-use preparations see section 6.3.

6.5 Nature and contents of container

- Bottles of low-density polyethylene (LD-PE),

contents: 50 ml, 100 ml, 250 ml, 500 ml, 1000 ml
pack sizes: 20 x 50 ml, 10 x 100 ml, 20 x 100 ml, 10 x 250 ml, 20 x 250 ml, 10 x 500 ml, 10 x 1000 ml

- Polyethylene ampoules,

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

- Polypropylene ampoules,

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

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements for disposal.
Only to be used if solution is clear, colourless and the container and 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

B. Braun Melsungen AG
Carl-Braun-Strasse 1
34212 Melsungen, Germany
Postal address:
34209 Melsungen, Germany

8. MARKETING AUTHORISATION NUMBER(S)

PL 03551/0077

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9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

18/10/2006

10 DATE OF REVISION OF THE TEXT

21/06/2015

Effective

Title: 0025L-SmPC-Water for Injections Ph Eur-GB-en Initiator: Marcus ? Thielemann

This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

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