# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Water for Injections Ph. Eur.

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains 1ml water for injections.

## 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 (see section 6.6).

### 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 Fertility, pregnancy and lactation

Pregnancy
Water for injections can be used during pregnancy as it does not bear any risks for the woman or child if used according to this product information.

The product information given for the medicinal product to be dissolved or diluted must also be taken into consideration, to evaluate whether the final prepared dilution or mixture 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 Ph. Eur. 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
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

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*

3 years

*After first opening*

Use the liquid immediately after opening of the container.

*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.

Recommendations given in the product information of the product diluted or mixed with water for injection should be taken into consideration for further information on compatibility and shelf life.

## 6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

For storage conditions after reconstitution, dilution and first opening of the medicinal product, see section 6.3.

## 6.5 Nature and contents of container

Round or oval polyethylene ampoules, contents: 10 ml, 20 ml. Pack sizes: 20 x 10 ml, 20 x 20 ml.

Polypropylene ampoules Mini-Plasco basic, contents: 10ml, 20ml. Pack sizes: 100 x 10 ml, 100 x 20 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.

Parenteral solution should be prepared under aseptic conditions.

Water for injection must only be administered after addition of osmotic active substances, as water for injections itself

is strongly hypotonic.

## 7 MARKETING AUTHORISATION HOLDER

B. Braun Medical Limited
3 Naas Road Industrial Park
Dublin 12

## 8 MARKETING AUTHORISATION NUMBER

PA 0179/009/003

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th April 1987

Date of last renewal: 8th April 2007

## 10 DATE OF REVISION OF THE TEXT

July 2015