

**SUMMARY OF PRODUCT CHARACTERISTICS**

## **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

#### *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  
pack sizes: 20 x 5 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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**2-Feb-22**

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