

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

WATER FOR INJECTIONS - FRESENIUS

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

1 ml solution contain:

Water for injections                      1 ml

### **3 PHARMACEUTICAL FORM**

Solvent for parenteral use

Clear, colourless liquid

### **4 CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

Preparation and dilution of medicines for parenteral administration.

#### **4.2 Posology and method of administration**

##### Posology

Water for injections – Fresenius 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 should be 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 product should be dissolved or diluted immediately before use.

#### **4.3 Contraindications**

There are no contraindications for Water for injections – Fresenius as such.

#### **4.4 Special warnings and precautions for use**

Water for injections – Fresenius 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 – Fresenius and other medicinal products are not known.

#### **4.6 Fertility, pregnancy and lactation**

##### Pregnancy

Generally, Water for injections – Fresenius can be used during pregnancy.

##### Breast-feeding

Water for injections – Fresenius can be used during breast-feeding.

##### Fertility

No data available.

#### **4.7 Effects on ability to drive and use machines**

Water for injections – Fresenius 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.

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form

<https://sideeffects.health.gov.il/>

and emailed to the Registration Holder's Patient Safety Unit at:  
drugsafety@neopharmgroup.com

#### **4.9 Overdose**

##### *Symptoms and treatment*

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

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Solvents and diluting agents, including irrigation solutions  
ATC code: V07AB

### **5.2 Pharmacokinetic properties**

None

### **5.3 Preclinical safety data**

Non-clinical data on Water for injections – Fresenius reveal no special hazards 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 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**

The expiry date of the product is indicated on the packaging materials.

### **6.4 Special precautions for storage**

Do not store above 25°C.

For storage conditions of ready-to-use preparation see section 6.3.

### **6.5 Nature and contents of container**

Ampoules LDPE. 20 x 5 ml, 50 x 5 ml, 20 x 10 ml, 50 x 10 ml, 20 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 the solution is clear and colourless, and the container and closure are undamaged. The containers are for single use only. After use discard the container and any remaining contents.

Use the liquid immediately after opening the container.

#### **7 MANUFACTURER**

Labesfal – Laboratorios Almiro s.a, Fresenius Kabi Group, Portugal  
Lagedo, Santiago De Besteiros, 3465 – 157, Portugal

#### **8 REGISTRATION HOLDER**

Neopharm (Israel) 1996 Ltd  
Hashiloach 6, POB 7063 Petach Tiqva 4917001

#### **9 LICENSE NUMBER**

163-26-34996-00

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*WFI Fresenius Solvent for Parenteral Use SPC vr01A*