**Approved professional information for WATER FOR INJECTIONS FRESENIUS**

**SCHEDULING STATUS**

**S1**

## 1. NAME OF THE MEDICINE

**WATER FOR INJECTIONS FRESENIUS diluent for injection**

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ampoule contains 2 ml, 5 ml, 10 ml or 20 ml of water for injection 100 % *v/v*.

Sugar free.

Sterile, pyrogen free.

## 3. PHARMACEUTICAL FORM

Diluent for injection.

Clear, colourless, sterile water for injection.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

For use as a solvent for parenteral products, such as sterile solids that must be distributed dry because of limited stability of their solutions, or for dilution of concentrated solutions.

### 4.2 Posology and method of administration

According to the concentration of the active ingredient required.

### 4.3 Contraindications

- WATER FOR INJECTIONS FRESENIUS should not be administered alone as it may cause haemolysis.
- The contraindications related to the added medicine should be considered prior to administration.

## 4.4 Special warnings and precautions for use

WATER FOR INJECTIONS FRESENIUS is hypotonic and it must not be administered alone, as it may cause haemolysis (see section 4.3).

## 4.5 Interaction with other medicines and other forms of interaction

There are no known interactions for WATER FOR INJECTIONS FRESENIUS.

The possible clinical interactions between the different medicines to be dissolved should be considered.

## 4.6 Fertility, pregnancy and lactation

WATER FOR INJECTIONS FRESENIUS may be used during fertility, pregnancy and lactation.

The risk during use is determined by the nature of the added medicines.

## 4.7 Effects on ability to drive and use machines

WATER FOR INJECTIONS FRESENIUS has no effect on the ability to drive or use machinery.

## 4.8 Undesirable effects

Not to be administered alone (see section 4.3).

The nature of the additive will determine the likelihood of any undesirable effects.

**Reporting of suspected adverse reactions:**

Reporting suspected adverse reactions after authorisation of WATER FOR INJECTIONS FRESENIUS is important. It allows continued monitoring of the benefit/risk balance of WATER FOR INJECTIONS FRESENIUS. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

### 4.9 Overdose

No effects are anticipated if used as instructed.

Haemolysis may occur following infusion of large volumes of hypotonic solutions using WATER FOR INJECTIONS FRESENIUS as diluent.

The signs and symptoms of overdose will also be related to the nature of the medicines being added. In the event of accidental overdose, the treatment should be discontinued, and the patient should be observed for the appropriate signs and symptoms related to the medicine administered.

## 5. PHARMACOLOGICAL PROPERTIES

Category and class: A 32.4 Water for injection

Pharmacotherapeutic group: Solvents and diluting agents, including irrigating solutions

ATC code: V07AB

Water for injection is a solvent for injectable aqueous solutions.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

None.

### 6.2 Incompatibilities

Additives may be incompatible. Compatibility of the additives with the solution must be assessed before addition. Those additives to be incompatible should not be used.

### 6.3 Shelf life

60 months.

Store at or below 25 ˚C.

### 6.4 Special precautions for storage

No special requirements.

### 6.5 Nature and contents of container

2 ml, 5 ml, 10 ml or 20 ml clear glass ampoules.

Pack size: 10 units.

Not all pack sizes may be marketed.

### 6.6 Special precautions for disposal and other handling

Discard unused portion.

Do not use unless solution is clear.

## 7. HOLDER OF CERTIFICATE OF REGISTRATION

Fresenius Kabi Manufacturing SA (Pty) Ltd

6 Gibaud Road

Korsten

Port Elizabeth 6020

South Africa

## 8. REGISTRATION NUMBER

G 2717 (Act 101/1965)

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

Not applicable.

## 10. DATE OF REVISION OF THE TEXT

09 January 2021