

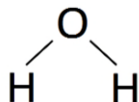
# NEW ZEALAND DATA SHEET

## Water for Injections BP

### 1 PRODUCT NAME

Water for Injections

The structural formula is represented below:



Molecular formula: H<sub>2</sub>O

Molecular weight: 18.02

CAS number: 7732-18-5

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Water for Injections BP Injection solution contains 100% v/v water for injections.

### 3 PHARMACEUTICAL FORM

Injection for Solution.

Water for Injections is a clear, colourless, particle-free, odourless and tasteless liquid. It is sterile, with a pH of 5.0-7.0 and contains no anti-microbial agents.

### 4 CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

Water for Injections is used to dissolve or dilute substances or preparations for parenteral administration.

Water for Injections may also be used as an irrigating solution for small wounds or during minor surgical procedures.

#### 4.2 Dose and method of administration

##### **For dissolving or diluting agents for parenteral administration**

The dosage for Water for Injections is that required to dissolve or dilute other agents. Aseptic technique must be used when preparing solutions for parenteral administration. Check the Product Information of any substance, preparation or drug before use to ensure appropriate solubility, dilution or compatibility with other additives.

Solutions prepared with Water for Injections may be administered intravenously, intramuscularly or subcutaneously using strict aseptic technique. Care should be exercised that all solutions prepared with Water for Injections are isotonic before use (See 4.4 Special Warnings and Precautions for Use). Water for Injections is for use for a single patient on a single occasion. Any residue should be discarded.

Usually solutions are prepared immediately before use. The Product Information of substances or drugs to be dissolved or diluted must be consulted to ascertain the maximum time between aseptic preparation and use of the solution.

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### **For irrigation**

Before using Water for Injections to irrigate small wounds, or during minor surgical procedures, inspect the contents to ensure that there has been no discolouration. Water for Injections is a sterile product and when used for irrigation, strict aseptic technique should be observed at all times. Water for Injections is for use for a single patient on a single occasion. Any residue remaining should be discarded.

### **4.3 Contraindications**

Water for Injection is hypotonic causing haemolysis if it is injected alone. It is contraindicated for intravenous administration if not adjusted to iso-tonicity by the addition of suitable solutes.

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

Before dissolving or diluting any substance or preparation, ensure that Water for Injections is the recommended solvent or diluent by consulting the Product Information for the substance, drug or preparation.

Ensure that the solution prepared with Water for Injections is isotonic with blood before intravenous administration.

For use in one patient on one occasion only. Discard any remaining portion.

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

None known.

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

#### Use in pregnancy (Category A)

Water for Injections has been administered to a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the foetus having been observed. Check the Product Information document of the drug to be dissolved or diluted to ensure that it is safe to use during pregnancy.

#### Use in lactation

Water for Injections can be administered to women who are breast-feeding. Check the Product Information document of the drug to be dissolved or diluted to ensure that it is safe to use during lactation.

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

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

### **4.8 Undesirable effects**

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No adverse reactions are known to be associated with Water for Injections. There should be no adverse reaction to Water for Injections if used as indicated to dissolve compatible substances to form an isotonic solution prior to injection. Injection of Water for Injections without the addition of solute may result in cell damage due to hypotonic effects (see 4.4 Special Warnings and Precautions for use and 4.9 Overdose).

The Product Information of any drug or substance used with Water for Injections BP must be consulted before use.

### 4.9 Overdose

Overdose with small volume presentations of Water for Injections is unlikely. If larger volumes of Water for Injections are inadvertently injected without first ensuring isotonicity, the hypotonic effects may include local cell damage or haemolysis. Electrolyte abnormalities are possible. The patient should be assessed and treated appropriately.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766) New Zealand.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Water is the main constituent of the body fluids. Body weight is approximately 60% of water distributed in intracellular, interstitial and vascular compartments. The water content in the intracellular fluid, i.e. the water inside the cells, is about 40 to 45 % of body weight. Water moves freely between these compartments. Thus, pharmacological action of the Water for Injection is as a vehicle for substances in maintaining the iso-tonicity across these compartments.

### 5.2 Pharmacokinetic properties

As Water for Injection is solute-free with osmolarity of zero (a hypotonic solution), its entry into the systemic circulation will result in a dilution of the electrolytes in the extracellular fluid leading to the movement of water into the red blood cells causing haemolysis. Thus, Water for Injection should not be injected without adjusting it to isotonicity by the addition of suitable solute.

### 5.3 Preclinical safety data

No data available

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

None

### 6.2 Incompatibilities

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

### 6.3 Shelf life

24 months

### 6.4 Special precautions for storage

Store below 25°C.

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## Water for Injections BP

### 6.5 Nature and contents of container

Water for Injections BP injection solution contains 100%v/v water for injections and is supplied in low density polyethylene (LDPE) ampoules in the following presentations:

Water for Injections BP 5 mL (packs of 20)

Water for Injections BP 10 mL (packs of 20 and 50)

Water for Injections BP 20 mL (packs of 20)

### 6.6 Special precautions for disposal

The expiry date (month/year) is stated on the package after EXP.

No special requirements for disposal

## 7 MEDICINE SCHEDULE

New Zealand: General Sales Medicine

## 8 SPONSOR

Fresenius Kabi New Zealand Limited,  
c/o GNZCC , HSBC Tower, Level 14, 188 Quay Street,  
Auckland 1010, New Zealand  
Freecall: 0800 144 892

## 9 DATE OF FIRST APPROVAL

30 Apr 2013

## 10 DATE OF REVISION OF THE TEXT

08/09/2021

## SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
8	Change of sponsor address