

AUSTRALIAN PRODUCT INFORMATION- WATER FOR INJECTION BP (WATER FOR INJECTION)

1 NAME OF MEDICINE

Water for Injections

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Solution for injection

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.

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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.

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 Injections is hypotonic causing haemolysis if it is injected alone. It is contraindicated for intravenous administration if not adjusted to isotonicity 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.

Use in the elderly

No data available

Paediatric Use

No data available

Effects on laboratory tests

No data available

4.5 INTERACTION WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

None known

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4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

None known

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 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

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.

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration 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 at www.tga.gov.au/reporting-problems.

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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 information on the management of overdose, contact the Poison Information Centre on 131126 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mechanism of action

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, ie. 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 isotonicity across these compartments.

Clinical trials

No data available

5.2 Pharmacokinetic properties

As Water for Injections 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 Injections should not be injected without adjusting it to isotonicity by the addition of suitable solute.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

Water is the main constituent of the body fluids and is not known as a mutagen

Carcinogenicity

Water is the main constituent of the body fluids and is not known as a carcinogen.

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6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Not applicable

6.2 INCOMPATIBILITIES

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

However, additives may be incompatible with Water for Injections BP (see Section 4.2 DOSE AND METHOD OF ADMINISTRATION'.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

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

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C.

6.5 NATURE AND CONTENTS OF CONTAINER

Water for Injections BP injection solution is supplied in low density polyethylene (LDPE) and polypropylene (PP) ampoules in the following presentations:

Water for Injections BP 5 mL AUST R 198332 (packs of 20)

Water for Injections BP 10 mL AUST R 198330 (packs of 20 and 50)

Water for Injections BP 20 mL AUST R 198331 (packs of 20)

*Not all pack sizes/volumes may be marketed.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

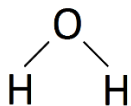
In Australia, any unused medicine or waste material should be disposed of in accordance with local requirements.

6.7 PHYSICOCHEMICAL PROPERTIES

Chemical structure

The chemical name for water is hydrogen oxide.

The structural formula is represented below:



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Molecular formula is H₂O.

Molecular weight: 18.02

CAS number

7732-18-5

7 MEDICINE SCHEDULE (POISONS STANDARD)

Australia: Not scheduled

8 SPONSOR

Fresenius Kabi Australia Pty Limited

Level 2, 2 Woodland Way

Mount Kuring-gai, NSW 2080

Australia

Telephone: (02) 9391 5555

9 DATE OF FIRST APPROVAL

30 Apr 2013

10 DATE OF REVISION OF THE TEXT

17 Aug 2023

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
4.9	NZ Poison Information Centre number removed
6.5	New polypropylene ampoule added Added *Not all pack sizes/volumes may be marketed.
7	NZ poison schedule removed
8	NZ sponsor details removed