

AUSTRALIAN PRODUCT INFORMATION WATER FOR INJECTIONS BP (WATER FOR INJECTIONS)

1. NAME OF THE MEDICINE

Water for injections

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Water for Injection BP is a non-isotonic, ready to use, single dose solution. It does not contain preservatives.

3. PHARMACEUTICAL FORM

Water for Injections BP is a sterile, non-isotonic, clear, colourless solution in a ready-to-use, single dose presentation. It does not contain preservatives.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Water for Injections is used for the reconstitution and preparation of aqueous injections.

4.2 Dose and method of administration

Dosage

Ensure appropriate solubility, dilution or compatibility with other additives and ascertain the maximum time between aseptic preparation and administration by consulting the Product Information of any substance, preparation or drug before use.

The dosage for Water for Injections is the amount required to reconstitute or prepare other agents. Ensure that all solutions prepared with Water for Injections are isotonic before use (see Section 4.4 Special warnings and precautions for use).

Aseptic technique must be used when preparing and administering solutions for parenteral use. Usually solutions are prepared immediately before use.

Solutions prepared with Water for Injections may be administered intravenously, intramuscularly or subcutaneously. Water for Injections is for use in one patient on one occasion only. Discard any residue.

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

Do not use Water for Injections unless it is clear and the seal is intact.

Before dissolving or diluting any substance or preparation, consult the Product Information for the substance, drug or preparation to ensure that Water for Injections is the recommended solvent or diluent, check appropriate solubility, dilution or compatibility with other additives.

Ensure that the solution prepared with Water for Injections is isotonic with blood before intravenous administration. Intravenous administration of water or hypotonic solution may cause haemolysis.

Use in the elderly

No data available

Paediatric use

No data available

Effects on laboratory tests

No data available

4.5 Interactions with other medicines and other forms of interactions

No data available

4.6 Fertility, pregnancy and lactation

Effects on fertility

No data available

Use in pregnancy – 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)

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

Injection of Water for Injections without the addition of solute may result in cell damage due to hypotonic effects (see Section 4.4 Special warnings and precautions for use and Section 4.9 Overdose). Haemolysis may lead to renal tubular obstruction. Expansion of intravascular fluid, through intravenous administration or systemic absorption of irrigation solutions, may result in electrolyte disturbances including hyponatraemia, and cardiovascular / pulmonary disorders due to oedema.

Other adverse reactions may include fever, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation, and hypervolemia. These may not necessarily be due to Water for Injections itself.

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.

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

No data available

Clinical trials

No data available

5.2 Pharmacokinetic properties

No data available

5.3 Preclinical safety data

Genotoxicity

No data available

Carcinogenicity

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.

Ensure appropriate solubility, dilution or compatibility with other additives and ascertain the maximum time between aseptic preparation and administration by consulting the Product Information of any substance, preparation or drug before use.

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

6.4 Special precautions for storage

Store below 25°C.

Use once only and discard any remaining portion.

6.5 Nature and contents of container

AUST R 49284 Water for Injection- BP 2mL Steriluer® ampoule (200s)

AUST R 49286 Water for Injection- BP 5mL Steriluer® ampoule (50s)

AUST R 49287 Water for Injection- BP 10mL Steriluer® ampoule (50s)

AUST R 49287 Water for Injection- BP 10mL Steriluer® ampoule (600s)
(Available in Australia only)

AUST R 49288 Water for Injection- BP 20mL Steriamp® ampoule (30s)

AUST R 49298 Water for Injections BP 100mL plastic vial (10s)

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

The chemical name for water is hydrogen oxide.

Chemical structure

Molecular Formula: H₂O

Molecular Weight: 18.02

CAS number

7732-18-5

7. MEDICINE SCHEDULE (POISONS STANDARD)

Australia - Nil.

8. SPONSOR

Pfizer Australia Pty Ltd
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9. DATE OF FIRST APPROVAL

11 August 2003

10. DATE OF REVISION

20 November 2019

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Summary Table of Changes

Section changed	Summary of new information
All	All sections reformatted in line with the new form.
1; 2; 4; 5; 6; 9; & 10	Editorial

8	Sponsor details updated
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