

WATER FOR INJECTION
Solution for Injection
(WATER FOR INJECTIONS)

1 NAME OF THE MEDICINE

Water for Injections

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Water for Injection is sterile, with a pH of 5.6-7.7. The water is first distilled and then filtered through two successive pre-sterilised 0.22 micron membrane filters.

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

3 PHARMACEUTICAL FORM

Water for Injection solution for injection is a clear, colourless, particle-free, odourless and tasteless liquid.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Water for Injection is used to dissolve or dilute substances or preparations for parenteral administration. It can also be used as a sterile irrigation solution for washing or irrigating patients.

4.2 DOSE AND METHOD OF ADMINISTRATION

The dosage for Water for Injection 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 Injection may be administered intravenously, intramuscularly or subcutaneously using strict aseptic technique. Care should be exercised that all solutions prepared with Water for Injection are isotonic before use (see Section 4.4 Special Warnings and Precautions for Use). Water for Injection 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.

4.3 CONTRAINDICATIONS

No data available.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Consult the product information document for the substance, drug or preparation to be dissolved or diluted, to ensure that Water for Injection is the recommended solvent or diluent before dissolving or diluting any substance

or preparation. Prior to using Water for Injection to dissolve or dilute any substances or preparations, check the compatibility of all additives and drugs.

Before intravenous administration of a solution prepared with Water for Injection, ensure that the resultant solution is isotonic with blood.

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

(Category A)

Water for Injection 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 Injection can be administered to women who are breastfeeding. 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 Injection. There should be no adverse reaction to Water for Injection if used as indicated to dissolve compatible substances to form an isotonic solution prior to injection. Injection of Water for Injection 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).

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

Reporting suspected adverse reactions

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 <http://www.tga.gov.au/reporting-problems>.

4.9 OVERDOSE

Overdose with small volume presentations of Water for Injection is unlikely. If larger volumes of Water for Injection 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 Poisons 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

Distribution

No data available.

Metabolism

No data available.

Excretion

No data available.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Water for Injection contains hydrochloric acid for pH adjustment. The injections contain no anti-microbial agents.

6.2 INCOMPATIBILITIES

PRODUCT INFORMATION

Water for Injection



Check the Product Information of any substance, preparation or drug before use to ensure appropriate solubility, dilution or compatibility with other additives.

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)¹. The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 30°C.

6.5 NATURE AND CONTENTS OF CONTAINER

Water for Injection 50 mL in a 50 mL glass vial.

Pack of 10 units.

Phebra Product Code - INJ075.

Water for Injection 100 mL in a 100 mL glass vial.

Pack of 10 units.

Phebra Product Code - INJ077.

The vial stopper is not made with natural rubber latex.

Not all presentations may be marketed.

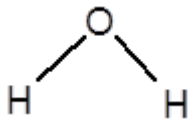
6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

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

6.7 PHYSICOCHEMICAL PROPERTIES

Chemical name: hydrogen oxide. Chemical formula is H₂O and molecular weight is 18.02.

Chemical structure



CAS number

7732-18-5

7 MEDICINE SCHEDULE (POISONS STANDARD)

Not scheduled

¹ AUST R 48353 (50 mL); AUST R 48354 (100 mL)

8 SPONSOR

Phebra² Pty Ltd, 19 Orion Road, Lane Cove West, NSW 2066, Australia.

Telephone: 1800 720 020

9 DATE OF FIRST APPROVAL

29 Oct 2002

10 DATE OF REVISION

28 April 2020

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
All	PI reformatted to align with new form
6.1	Minor editorial update
6.5	Minor editorial update

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