

PRODUCT INFORMATION

WATER FOR INJECTIONS BP

NAME OF THE MEDICINE

Water for Injections BP

Molecular Formula: H₂O

Molecular Weight: 18.02

CAS Number: 7732-18-5

DESCRIPTION

The chemical name for water is hydrogen oxide.

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.

INDICATIONS

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

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.

PRECAUTIONS

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 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.

ADVERSE 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 **PRECAUTIONS** and **OVERDOSAGE**). 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.

DOSAGE AND ADMINISTRATION

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 **PRECAUTIONS**).

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.

OVERDOSAGE

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.

PRESENTATION AND STORAGE CONDITIONS

AUST R 49284	Water for Injections BP	2mL Steriluer [®] ampoule (200s)
AUST R 49286	Water for Injections BP	5mL Steriluer [®] ampoule (50s)
AUST R 49287	Water for Injections BP	10mL Steriluer [®] ampoule (50s)
AUST R 49287 (Available in Australia only)	Water for Injections BP	10mL Steriluer [®] ampoule (600s)
AUST R 49288	Water for Injections BP	20mL Steriamp [®] ampoule (30s)
AUST R 49298	Water for Injections BP	100mL plastic vial (10s)

Store below 25°C.

Use once only and discard any remaining portion.

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

MANUFACTURER

Pfizer (Perth) Pty Limited
ABN 32 051 824 956
15 Brodie Hall Drive,
Bentley WA 6102 Australia

Distributed in Australia by:

Pfizer Australia Pty Ltd
ABN 50 008 422 348
38-42 Wharf Road
West Ryde NSW 2114 Australia

SPONSOR IN AUSTRALIA:

Pfizer Australia Pty Ltd
ABN 50 008 422 348
38-42 Wharf Road
West Ryde NSW 2114 Australia

POISON SCHEDULE

Australia - Nil.

DATE OF APPROVAL

This information was approved by the TGA on 11 August 2003

Date of most recent amendment: 26 October 2012

® Registered Trademark