

WATER FOR INJECTIONS BP

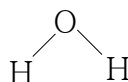
PRODUCT INFORMATION

NAME OF THE MEDICINE

Water for Injections BP

The CAS number for water is 7732-18-5. The chemical name for water is hydrogen oxide. Its chemical formula is H₂O and its molecular weight is 18.02.

The chemical structure of water is:



DESCRIPTION

Water for Injections BP is a clear, colourless, particle-free, odourless and tasteless liquid. It is sterile, with a pH of 5.6-7.7 and contains no anti-microbial agents. The water is first distilled and then filtered through two successive pre-sterilised 0.22 micron membrane filters.

INDICATIONS

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

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

PRECAUTIONS

Consult the Product Information document for the substance, drug or preparation to be dissolved or diluted, to ensure that Water for Injections BP is the recommended solvent or diluent before dissolving or diluting any substance or preparation. Prior to using Water for Injections BP 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 Injections BP, ensure that the resultant solution is isotonic with blood.

Use in Pregnancy Category A

Water for Injections BP 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 BP 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.

ADVERSE REACTIONS

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 PRECAUTIONS, OVERDOSAGE).

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

DOSAGE AND ADMINISTRATION

For dissolving or diluting agents for parenteral administration

The dosage for Water for Injections BP 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 BP may be administered intravenously, intramuscularly or subcutaneously using strict aseptic technique. Care should be exercised that all solutions prepared with Water for Injections BP are isotonic before use (SEE PRECAUTIONS). Water for Injections BP 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.

For irrigation

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

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

Clear, particle-free, colourless, sterile liquid used to dissolve or dilute other agents for intravenous, intramuscular or subcutaneous injection.

Glass ampoules (not marketed)

2 mL – packs of 5 and 50, store below 30°C, shelf life 5 years

5 and 10 mL – packs of 5, 10 and 50, store below 30°C, shelf life 5 years

Polyethylene plastic Polyamp DuoFit®

5 mL – packs of 5[^], 10[^] and 50, store below 25°C, shelf life 2 years

10 mL – packs of 5[^], 10[^], 50 and 400, store below 30°C, shelf life 2 years

[^] not marketed

NAME AND ADDRESS OF SPONSOR

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NSW 2113 Australia

POISON SCHEDULE OF THE DRUG Unscheduled

DATE OF APPROVAL

Date of TGA Approval: 24 July 2003

Date of most recent amendment: 21 March 2013

Polyamp DuoFit is a trade mark of the AstraZeneca group of companies