

PRODUCT INFORMATION

Name of the medicine

Water for injections Freeflex

The CAS number for water is 7732-18-5.

The chemical name for water is hydrogen oxide.

Its chemical formula is H₂O

Molecular Weight: 18.02.

Description

Water for Injections is a clear, colourless, particle-free, odourless and tasteless liquid with a pH of 5.6-7.7. It contains no anti-microbial agents.

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.

Contraindications

Water for Injections is hypotonic causing haemolysis if it is injected alone. It is contraindicated for intravenous administration if it is not adjusted to isotonicity by the addition of suitable solutes.

The use of Water for Injection as irrigation during a major surgical procedure, or in a procedure where significant amounts may be absorbed or enter the circulation, is contraindicated.

Precautions

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

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

Before intravenous administration of a solution prepared with Water for Injections, ensure that the resultant solution is isotonic with blood. Entry of water or hypotonic solution into the systemic circulation may cause haemolysis. Given that there is a possibility of systemic absorption of irrigation solutions, the same precautions apply.

Tissue damage may result from irrigation with large volumes or under pressure: see Adverse Reactions.

Use in Pregnancy (Category A)

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 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

Haemolysis and hyponatraemia have been reported after irrigation during urological procedure. 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). Haemolysis may lead to renal tubular obstruction. Expansion of intravascular fluid, through intravenous infusion, or systemic absorption of irrigation solutions, may result in electrolyte disturbances including hyponatraemia, and cardiovascular/pulmonary disorders due to oedema.

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

Intravenous administration of solutions may cause local reactions including pain, vein irritation, and thrombophlebitis. Extravasation of solution may cause tissue injury.

Displaced catheters or drainage tubes can lead to irrigation or infiltration of unintended structures or cavities. Excessive volumes or pressure during irrigation of closed cavities may result in distension or disruption of tissues. Inadvertent contamination from careless techniques may transmit infection.

Dosage and 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 Precautions). Water for Injections is to be used for one patient on one occasion only. Any residue should be discarded. It does not contain antimicrobials. Care should be taken with intravenous administration and injection technique to avoid injection site reactions and infections.

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.

Overdosage

If Water for Injections is inadvertently injected without first ensuring isotonicity, the hypotonic effects may include local cell damage or haemolysis.

Overdose using isotonic intravenous solutions prepared using Water for Injections or during irrigation, may cause fluid overload and electrolyte disturbances. See Adverse Reactions.

Infusion or irrigation should be ceased and the patient assessed and treated appropriately.

Presentation and storage conditions

Freeflex bags - Store below 25°C.

100mL AUST R 144795

250mL AUST R 144808

500mL AUST R 144809

1000mL AUST R 144814

Name and address of the sponsor

Fresenius Kabi Australia Pty Limited
Level 2, 2 Woodland Way
Mount Kuring-gai NSW 2080
Australia
Telephone: (61-2) 9391 5555

Fresenius Kabi New Zealand Limited
60 Pavilion Drive
Airport Oaks, Auckland 2022
New Zealand
Freecall: 0800 144 892

Poison schedule of the medicine

Australia: Nil.
New Zealand: General Sales Medicine

Date of first inclusion in the ARTG

11 August 2005

Date of most recent amendment

25 May 2016