

NEW ZEALAND DATA SHEET

1 PRODUCT NAME

Water for injections Freeflex

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Water for Injections 100%

3 PHARMACEUTICAL FORM

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.

4 CLINICAL PARTICULARS

4.1 Therapeutic 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.

4.2 Dose and method of 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.

NEW ZEALAND DATA SHEET

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.

4.3 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.

4.4 Special warnings and precautions for use

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 Undesirable Effects.

4.5 Interaction with other medicines and other forms of interaction

Not applicable

4.6 Fertility, pregnancy and lactation

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.

NEW ZEALAND DATA SHEET

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.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

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.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions <https://nzphvc.otago.ac.nz/reporting/>.

4.9 Overdose

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

NEW ZEALAND DATA SHEET

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.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Not applicable.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

50mL, 100mL – 24 months

250mL, 500mL, 1000mL – 36 months

6.4 Special precautions for storage

Store below 25°C

6.5 Nature and contents of container

Freeflex bags

6.6 Special precautions for disposal

No special requirements for disposal

7 MEDICINE SCHEDULE

Australia: Nil.

New Zealand: General Sales Medicine

NEW ZEALAND DATA SHEET

8 SPONSOR

Fresenius Kabi New Zealand Limited,
c/o GNZCC , HSBC Tower, Level 14, 188 Quay Street,
Auckland 1010, New Zealand
Freecall: 0800 144 892

9 DATE OF FIRST APPROVAL

19 September 2007

10 DATE OF REVISION OF THE TEXT

08/09/2021

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
8	Sponsor address change