1 WATER FOR INJECTION (100% solution for infusion)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients

Sterilised **Water for Injection**, BP.

The composition of the sterilised **Water for Injection** is sterile water only. It does not contain any antimicrobial agent.

3 PHARMACEUTICAL FORM

Solution for infusion.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Sterilised **Water for Injection** is employed as a vehicle for medicinal products when water is a suitable solvent for dissolving or diluting injectable therapeutic substances for parenteral administration.

4.2 Dose and method of administration

Dosage

As sterilised **Water for Injection** is indicated only as a vehicle for aseptic reconstituting and administration of medicine admixture, the dosage limitations are not applicable to this product.

Do not administer sterilised **Water for Injection** unless it has been adjusted to an isotonic solution by using suitable solute. The medical literature, the package insert and other available sources of information for the intended therapeutic agent should be reviewed for information and incompatibility problems.

Admixtures using **Water for Injection** as a vehicle should be inspected visually for particulate matter and discolouration prior to the administration whenever solution and container permit. Additives may be incompatible, and complete information on all of these is not available. Those additives known to be incompatible with water or the Viaflex plastic bag should not be used.

Direction for use

Do not use Viaflex plastic bags in series connections. Such use could result in embolism due to residual air being drawn from the primary bag before administration of the fluid from the secondary bag container is completed.

To open

Tear the over pouch sharply downwards at the slit and remove the Viaflex plastic bag. Some opacity of the plastic bag may be observed. This is due to moisture absorption during the sterilisation process. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard the solution, as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for administration

Suspend container from eyelet support.

Remove the blue plastic protector from the administration outlet port at the bottom of container.

Attach administration set.

To add medication
Additives may be incompatible.

To add medication BEFORE solution administration
Hold bag with ports uppermost. Decontaminate the medication site with an agent in accordance with the institution's Infection Control Policy. Using a syringe with a 19 to 22-gauge needle (0.90 – 0.7mm), puncture the re-sealable medication site and inject. Mix solution and medication thoroughly. Squeeze ports while the bags are upright and mix the solutions thoroughly.

To add medication DURING solution administration
Close clamp on the set. Decontaminate the medication site. Using syringe with 19 to 22-gauge needle (0.90 – 0.7mm), puncture re-sealable medication site and inject. Remove container from IV pole and/or turn to upright position. Empty both ports by squeezing them while container is in the upright position. Mix solution and medication thoroughly. Return container to its in-use position and continue administration.

4.3 Contraindications
Water for Injection 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.

4.4 Special warnings and precautions for use
General
The safety of the Viaflex plastic bag containing Water for Injection has been confirmed in tests with animals as well as by tissue culture toxicity studies. Nevertheless, prior to addition of medicines into the bags, compatibility with the container should be ascertained (see section 4.2).

The medical literature, the package insert and other available sources of information should be reviewed for thorough understanding of possible of incompatibility problems. In particular, Water for Injection is slightly acidic resulting from a low level of HCl released from the Viaflex plastic bags during the sterilisation, pH of 5.5 (mean of and range of 4.5 – 7.0), which may cause degradation or precipitation of certain medicines.

Do not administer Water for Injection unless it has been adjusted to an approximately isotonic solution by using a suitable solute. Intravenous administration of Water for Injection without added solute is contraindicated as it causes haemolysis. Haemoglobin induced renal failure has been reported following haemolysis. Do not use Water for Injection unless the solution is clear and seal is intact.

4.5 Interaction with other medicines and other forms of interaction
The possible clinical interactions between the different medicinal products to be added, should be considered.

4.6 Fertility, pregnancy and lactation
Fertility
Fertility studies have not been conducted.

The risks during use are determined by the nature of the added medicinal products.

Pregnancy
Intravenous administration of Water for Injection without added solute to non-pregnant or pregnant women is contraindicated as it causes haemolysis.

Lactation
Water is the main constituent of the body fluid and moves freely into nursing mother's milk. Even though no direct effect to the infant, intravenous administration of **Water for Injection** without added solutes should not be attempted because it causes haemolysis, resulting in harm to the nursing mother.

4.7 Effects on ability to drive and use machines
Water for Injection has no influence on the ability to drive and use machines.

4.8 Undesirable effects
Intravenous administration of **Water for Injection** without added solutes causes haemolysis. Even in the presence of added substances, they may be insufficient to render the solution isotonic. Administration of such an admixture may still be associated with adverse reactions. 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 necessary be due to the **Water for Injection** itself. There is also a possibility of unintentional hospital acquired infections.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient's status, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continuing monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https:// pophealth.my.site.com/carmreportnz/s/

4.9 Overdose
For risk assessment and advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764 766).

5 PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic group:	ATC Code:
Solvents and diluting agents, including irrigating solutions.	V07AB.

Water is the main constituent of the body fluids. Body weight is approximately 60% of water distributed in intracellular, interstitial and vascular compartments. The water content in the intracellular fluid, i.e. the water inside the cells, is about 40 to 45 % of body weight. Water moves freely between these compartments. Thus, pharmacological action of the **Water for Injection** is as a vehicle for substances in maintaining the isotonicity across these compartments.

As **Water for Injection** is solute-free with osmolarity of zero (a hypotonic solution), its entry into the systemic circulation will result in a dilution of the electrolytes in the extracellular fluid leading to the movement of water into the red blood cells causing haemolysis. Thus, **Water for Injection** should not be injected without adjusting it to isotonicity by the addition of suitable solute.

Chemical structure
H_2O

5.2 Pharmacokinetic properties

Water for Injections being only the vehicle for the administration of the added medicinal product, the pharmacokinetics will depend on the nature of the drug added.

5.3 Preclinical safety data

Carcinogenicity/mutagenicity

Water is the main constituent of the body fluids and is known neither as a carcinogen nor mutagen.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

The composition of the sterilised Water for Injection is sterile water only. It does not contain any excipients.

6.2 Incompatibilities

Additives may be incompatible (see section 4.2).

6.3 Shelf life

12 months from date of manufacture.

6.4 Special precautions for storage

Store at or below 30°C.

6.5 Nature and contents of container

Water for Injection is supplied in Viaflex plastic bags as a single unit dose. They are available in 1000mL single dose container as shown in Table 1.

Table 1: Sterile Water for Injection in Viaflex plastic bag products

Code No.	Name of the active components [concentrations (%, mmol/1000mL)]	Osmolarity (mOsmol/L)	TT50-	Pack size (mL)
AHB0304	Water for injection (no antibacterial agent added)	0 (zero)	5537/2	1000 (1's)

6.6 Special precautions for disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MEDICINE SCHEDULE

General Sale Medicine.

8 SPONSOR

Water for Injection is distributed in New Zealand by:

Baxter Healthcare Ltd
33 Vestey Drive
Mt Wellington
Auckland 1060.

Baxter Healthcare Ltd
PO Box 14 062
Panmure
Auckland 1741

Phone (09) 574 2400.

9 DATE OF FIRST APPROVAL

Date of publication in the New Zealand Gazette of consent to distribute the medicine:
6 September 1977.

10 DATE OF REVISION OF THE TEXT

2 December 2025.

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
4.8	Reporting suspected adverse reactions url updated.
4.9	Overdose contact details updated.
6.3	Shelf-life updates.
8	Sponsor details section updated.

Based on Australian PI approved 30 September 1991, most recent amendment 17 October 2014; and RSI sWFI2014June30.

Please refer to the Medsafe website (www.medsafe.govt.nz) for most recent data sheet.