NEW ZEALAND DATA SHEET

1. PRODUCT NAME

Water for Injections BP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Water for Injections BP

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Dose and method of administration

Ensure appropriate solubility, dilution or compatibility with other additives and ascertain the maximum time between aseptic preparation and administration by consulting the Data Sheet 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 section 4.4).

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.

4.3 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.

4.4 Special warnings and precautions for use

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 Data Sheet 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.

4.5 Interaction with other medicines and other forms of interaction

No Data Available

4.6 Fertility, pregnancy and lactation

Fertility

No Data Available

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 fetus having been observed. Check the Data Sheet document of the drug to be dissolved or diluted to ensure that it is safe to use during pregnancy.

Lactation

Water for Injections can be administered to women who are breast-feeding. Check the Data Sheet 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 machinery

No Data Available

4.8 Undesirable 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 Data Sheet 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 sections 4.4 and 4.9). 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 hypervolaemia. These may not necessarily be due to Water for Injections itself.

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

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.

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

No Data Available

5.2 Pharmacokinetic properties

No Data Available

5.3 Preclinical safety data

Genotoxicity

No Data Available

Carcinogenicity

No Data Available

Reproductive and developmental toxicity

No Data Available

6. PHARMACEUTICAL PARTICUALRS

6.1 List of excipients

None

6.2 Incompatibilities

No Data Available

6.3 Shelf life

24 months.

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

6.4 Special precautions for storage

Store below 25°C.

Use once only and discard any remaining portion.

6.5 Nature and contents of container

Water for Injections BP	5mL ampoule (50s)
Water for Injections BP	10mL ampoule (50s)
Water for Injections BP	20mL ampoule (30s)

* not all presentations may be marketed.

6.6 Special precautions for disposal

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

7. MEDICINE SCHEDULE

General Sale Medicine

8. SPONSOR

LumaCina New Zealand
C/o Quigg Partners
Level 7, The Bayleys Building
36 Brandon Street,
Wellington 6011, New Zealand

Telephone: 0800 822 634
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9. DATE OF FIRST APPROVAL

28 November 1988

10. DATE OF REVISION OF THE TEXT

20 October 2023.

Summary table of changes

Section changed	Summary of new information
5.1	Editorial update to include statement “No Data Available”
6.5	Editorial update to removal of trademarked text/information
8	Sponsor details updated