Water for Injections

1. Name of the medicinal product

Water for Injections.

2. Qualitative and quantitative composition

Each bag contains 100 % w/v Water for Injections.

3. Pharmaceutical form

Solvent for parenteral use. It is clear, colorless diluent.

4. Clinical particulars

4.1. Therapeutic indications

Sterile Water for Injection is indicated to serve as a vehicle for dilution and reconstitution of suitable medicinal products for parenteral administration.

4.2. Posology and method of administration

Posology

The dosage administered will be dictated by the nature of the additive used. The administration rate will be dependent upon the dose regimen of the prescribed drug.

Following suitable admixture of prescribed additives, the dosage is usually dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations.

Method of administration

The solution is for dilution and delivery of the therapeutic additives. The directions for use related to the added medicinal product will dictate the appropriate volumes as well as the administration route.

4.3. Contraindications

Water for Injections should not be administered alone.

The contraindications related to the added medicinal product should be considered.

4.4. Special warnings and precautions for use

Water for Injections is hypotonic and should not be administered alone.

Do not use for intravenous injection unless adjusted to approximate isotonicity with a suitable solute.

When Water for Injections is used as diluent of hypertonic solutions, appropriate dilution should be applied to bring the solution close to isotonicity.

Haemolysis may occur following infusion of Sterile Water for Injections. Haemoglobin induced renal failure has been reported following haemolysis.

When administering large volumes, the ionic balance should be regularly monitored.

The large volume presentations (500 and 1000ml) are for use as a bulk source of diluent in pharmacy compounding. They are not for direct intravenous administration.

4.5. Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.The possible clinical interactions between the different medicinal products tobe dissolved should be considered.

4.6. Fertility, pregnancy and lactation

The risks during use in pregnancy and in lactating women are determined by the nature of the added medicinal products.

4.7. Effects on ability to drive and use machines

Not relevant.

4.8. Undesirable effects

The following adverse reactions have been reported in post-marketing experience. The frequency of the adverse drug reactions listed in this section cannot be estimated from the available data.

ADVERSE REACTIONS		
System Organ Class (SOC)	MedDRA Preferred Term *Frequency*	
Blood and lymphatic systemdisorders	- haemolysis	Not known

The nature of the additive will determine the likelihood of any other undesirable effects.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the via the TMDA ADR reporting tool; website: https://imis.tmda.go.tz/arrt or search for TMDA Adverse Reactions Reporting Tool in the Google Play Store";

4.9. Overdose

Haemolysis may occur following over-infusion of hypotonic solutions using sterile water for injections as diluent (see 4.4Warnings and Precautions).

The signs and symptoms of overdose will also be related to the nature of the medicinal product being added. In the event of accidental overdose, the treatment should be discontinued and the patient should be observed for the appropriate signs and symptoms related to the medicinal product administered.

5. Pharmacological properties

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Solvents and Diluting

Agents. **ATC code: VO7AB.**

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

5.2. Pharmacokinetic properties

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

5.3. Preclinical safety data

Water for Injections being only the vehicle for the administration of the added medicinal product, the preclinical safetydata for the solutions in use will depend on the nature of the drug added.

6. Pharmaceutical particulars

6.1. List of excipients

None.

6.2. Incompatibilities

Additives may be incompatible. Those additives known to be incompatible should not be used. Before adding drugs,verify:

- They are soluble and stable in water at the pH of Water for Injections.
- They are compatible with each other.

6.3. Shelf life

24 months

6.4. Special precautions for storage

Store below 30°C.
Protect from light. Store in the original package. Do not Freeze.

6.5. Nature and contents of container

Sterile water for injection is supplied in PP bottles. Pack size: 96 bottles.

6.6. Special precautions for disposal

For single use only. Any unused solution should be discarded.

7. Marketing authorization holder

Kairuki Pharmaceuticals Industry Limited
Address: 192 Zegereni Industrial Area, Kibaha, Pwani.
E-Mail: info@kairukipharmaceuticals.org

8. Marketing authorization number(s)

TAN 22 HM 0423

9. Date of first authorization/renewal of the authorization

23rd September, 2022

10. Date of revision of the text