SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Water for Injection (Sterile Water for Injection, 10 ml)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Water for Injections BP, 100% w/v.

This product contains no active pharmaceutical ingredient, preservative, or other additive.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solvent for parenteral use.

A clear, colourless, sterile, pyrogen-free liquid, free from visible particles.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Water for Injections is indicated as a vehicle/diluent for the reconstitution or dilution of powders, concentrates or liquids for parenteral administration (intravenous, intramuscular or subcutaneous injection), according to the instructions of the manufacturer of the drug to be administered. It is also used for the preparation of pharmaceutical solutions when made isotonic by the addition of suitable solutes prior to use.

4.2 Posology and method of administration

Water for Injections must be made approximately isotonic prior to use by addition of suitable solutes; it must not be administered by intravenous injection or infusion in its unmodified (non-isotonic) form because of the risk of haemolysis.

The volume used for diluting or dissolving a drug for injection depends on the vehicle concentration, dose and route of administration recommended by the manufacturer of that drug.

Method of administration: For intravenous, intramuscular, or subcutaneous use only after admixture with, or dissolution of, the intended medicinal product, as directed by the manufacturer of that product.

4.3 Contraindications

Water for Injections must not be administered by intravenous injection or infusion without first rendering the solution approximately isotonic by the addition of an appropriate solute. Administration of hypotonic (non-isotonic) solutions can cause haemolysis.

Hypersensitivity is not applicable, as the product contains no active substance; however, hypersensitivity to any subsequently added medicinal product should be considered per that product's own labelling.

4.4 Special warnings and precautions for use

Water for Injections is intended solely as a vehicle for the preparation of injectable solutions. It contains no antimicrobial preservative; therefore, once the container is opened or a drug is added, the resulting solution should be used promptly or, if not used immediately, sterility must be maintained, and the solution should be discarded if not used within the timeframe recommended by the manufacturer of the added drug.

Discard any unused portion. Do not reuse single-dose containers.

Do not use unless the solution is clear, colourless, and free from visible particles, and the container seal is intact.

When used to reconstitute or dilute other medicinal products, the compatibility, stability and specific handling instructions of the medicinal product to be added must always be checked, as some drugs for injection may be incompatible with water alone or when combined in the same vehicle.

Care must be taken to ensure aseptic technique during reconstitution or dilution to reduce the risk of contamination and subsequent infection.

4.5 Interaction with other medicinal products and other forms of interaction

As Water for Injections contains no active pharmacological substance, no direct pharmacodynamic or pharmacokinetic interactions occur. However, some drugs for injection may be physically or chemically incompatible when reconstituted or diluted in water alone, or when combined with other diluents in the same vehicle. The pharmacist or manufacturer's product information for the drug being reconstituted or diluted should always be consulted before use.

4.6 Fertility, pregnancy and lactation

As Water for Injections contains no active pharmaceutical ingredient, no specific restrictions apply to its use in pregnancy, lactation or fertility when used solely as a diluent or vehicle. The safety of any medicinal product reconstituted or diluted with Water for Injections in pregnancy or lactation should be assessed according to that product's own prescribing information.

4.7 Effects on ability to drive and use machines

Not applicable, as the product contains no active pharmaceutical ingredient when used alone as a diluent.

4.8 Undesirable effects

Reactions which may occur as a result of the solution, technique of administration, or added drugs include: febrile response, local tenderness, abscess at the site of injection, tissue necrosis or infection at the injection site, venous thrombosis or phlebitis extending from the injection site, extravasation, and hypervolaemia.

If an adverse reaction does occur, the infusion or injection should be discontinued immediately, the patient evaluated, appropriate countermeasures instituted, and, if possible, the remainder of the unused product retained for examination.

Rapid infusion of large volumes of hypotonic (non-isotonic) solution may cause haemolysis, hyponatraemia and cerebral oedema.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are requested to report any suspected adverse reactions via the Pharmacy and Poisons Board, Pharmacovigilance Electronic Reporting System (PvERS):

https://pv.pharmacyboardkenya.org

4.9 Overdose

Excessive administration of hypotonic solutions prepared with Water for Injections may result in water intoxication, characterised by hyponatraemia, cerebral oedema, and haemolysis. Treatment should be symptomatic and supportive, with discontinuation of the infusion, correction of fluid and electrolyte imbalance, and monitoring of serum electrolytes and neurological status.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Solvents and diluting agents, including irrigating solutions.

ATC code: V07AB.

Water for Injections has no pharmacodynamic activity of its own. It functions solely as a sterile, pyrogen-free vehicle for the reconstitution or dilution of medicinal products for parenteral administration.

5.2 Pharmacokinetic properties

Not applicable, as Water for Injections contains no active pharmaceutical ingredient. When administered as part of an isotonic solution, water distributes freely across all body fluid compartments in line with normal physiological water balance.

5.3 Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None. This product consists solely of Water for Injections BP.

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6 or as directed by the manufacturer of the drug to be reconstituted or diluted.

6.3 Shelf life

….. years unopened.

Once opened or a drug has been added, use promptly; discard any unused portion.

6.4 Special precautions for storage

Store below 30°C. Do not freeze. Store in the original package.

6.5 Nature and contents of container

6.6 Special precautions for disposal and other handling

For single use only. Discard any unused portion. Inspect visually for particulate matter and discoloration prior to use, whenever solution and container permit; do not use if the solution is not clear or if the container seal is not intact. Any unused product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorization Holder

United Pharma (K) Limited,

Nairobi, Kenya.

8. Marketing Authorization Number

H2006/549/R1

9. Date of registration

10. Date of revision of the text

04 September 2026