National Agency for Food & Drug Administration & Control (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) TEMPLATE

1. NAME OF THE MEDICINAL PRODUCT

Name: Sterilised Water for Injections BP
Strength: Not applicable
Pharmaceutical form: Solution for intravenous infusion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sr. No.	Name of Ingredients	Specifications	Qt. per container (10 mL)	Used As
1.	Water for Injections	BP	q.s. to 10 mL	Diluent/Solvent/Irrigant

3. PHARMACEUTICAL FORM

Solution for intravenous infusion

CLINICAL PARTICULARS

4.1 Therapeutic indication

For the reconstitution, dilution and making-up of appropriate drugs where Sterilised Water for Injections BP is the diluent of choice, and for use as an irrigant.

4.2 Posology and method of administration

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 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

Sterilised Water for Injections BP should not be administered alone. The contraindications related to the added medicinal product should be considered.

4.4 Special warnings and precautions for use

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

Do not use for intravenous injection unless adjusted to approximate isotonicity with a suitable solute. When Sterilised Water for Injections BP is used as a diluent for hypertonic solutions, appropriate dilution should be applied to bring the solution close to isotonicity.

Haemolysis may occur following infusion of large volumes of hypotonic solutions using sterile Water for Injections as a diluent. When administering large volumes, the ionic balance should be

regularly monitored. The large volume presentations (500 mL and 1000 mL) 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
None known.

The possible clinical interactions between the different medicinal products to be dissolved should be considered.

4.6 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
Intravenous injections of Sterilised Water for Injections BP may cause haemolysis if it is administered alone. The nature of the additive will determine the likelihood of any other undesirable effects.

4.9 Overdose
Haemolysis may occur following infusion of large volumes of hypotonic solutions using sterile water for injections BP as diluent. 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 and ATC code: V07AB – solvents and diluting agents including irrigating solutions

5.2 Pharmacokinetic properties
Not Applicable

5.3 Preclinical safety data
Sterilised Water for Injections BP being only the vehicle for the administration of the added medicinal product, the preclinical safety data will depend on the nature of the drug added.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
None

6.2 Incompatibilities
Sterilised Water for Injections BP should not be mixed with any other agents unless established.

6.3 Shelf life

36 months from the date of manufacturing

6.4 Special precautions for storage
Store at a temperature not exceeding 30°C. Avoid freezing and excessive heat.

6.5 Nature and contents of container
Sterilised Water for Injections BP is available in 10 mL in Plastic Ampoule.

6.6 Special precautions for disposal
As appropriate to the reconstituted drug.
If only part of an ampoule is used, discard the remaining solution.
Use as directed by the physician.

7. APPLICANT
Geneith Pharmaceuticals Limited
12 Adewale Crescent, Off Ewenla Street,
Off Oshodi-Apapa Expressway, Oshodi, Lagos.

8. MANUFACTURER
Otsuka Pharmaceutical India Private Limited
Survey No.199 to 201 & 208 to 210,
Village – Vasana – Chacharwadi,
Tal- Sanand,
Dist: Ahmedabad – 382 213, India.