SUMMARY OF PRODUCT CHARACTERISTICS
STERILIZED WATER FOR INJECTION B.P(SWFI)

1. Name of the medicinal product

Sterilized Water For Injection B.P

2. Qualitative and quantitative composition

Each ampoule contains 100 % v/v Water for Injections.

3. Pharmaceutical form

Solvent for parenteral use

Clear, colourless, odourless, sterile solution intended for parenteral administration

4. Clinical particulars

4.1 Therapeutic indications

Water for Injections is indicated to be used 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.

The solution should only be used if it is clear without visible particles.

Method of administration

For parenteral use.

The directions for use will be dependent upon the appropriate medicinal product to which this solvent is added, which will dictate the appropriate volumes as well as administration route.

4.3 Contraindications

Water for Injections should not be administered alone because it may cause haemolysis. 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 it should not be administered alone, because it may cause haemolysis.

4.5 Interaction with other medicinal products and other forms of interaction

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

4.6 Pregnancy and lactation

May be used during fertility, pregnancy and lactation.

The risks during use 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

May cause haemolysis if administered alone.

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

4.9 Overdose

No effects are anticipated if used as instructed.

Haemolysis may occur following infusion of large volumes of hypotonic solutions using sterile water for injections 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: **Solvents and Diluting Agents**

ATC code: **V07AB**

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

Water for Injections 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

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N/A

6.2 Incompatibilities

Water for Injections should not be mixed with any other agents unless their compatibility has been established.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 30°C and do not freeze.

6.5 Nature and contents of container

Pack sizes: 10mL/5mL

The ampoules are made of low density polyethylene (LDPE).

6.6 Special precautions for disposal and other handling

For single use only.

As appropriate to the reconstituted drug.

If only part of an ampoule is used, discard the remaining solution.

Use as directed by the physician.

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

7. Marketing authorisation holder

Abacus Parenteral Drugs Ltd. Uganda

Block 191, Plot no.114, Kinga Mukono

P.O.Box 31376, Kampala, Uganda.

8. Marketing authorisation number

7151/26/10

9. Date of first authorisation/renewal of the authorization

OCT 2010

10. Date of revision of the text

16/05/2019