SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Sterilized Water for Injections BP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ampoule contains Sterilized Water for Injections BP

3. PHARMACEUTICAL FORM

Diluent for parenteral use.

Single-use FFS plastic ampoule containing 5-10 mL of Sterilized Water for Injections BP

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Sterilized Water for Injections is indicated to be used as a diluent and for reconstitution of suitable medicinal products for parenteral administration.

4.2 Posology and method of administration

Posology

- Posology - The dosage of Sterilized Water for Injections is not relevant.

The dosage will be dictated by the nature of the drug to be diluent.

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 isadded, which will dictate the appropriate volumes as well as administration route.

4.3 Contraindications

Sterilized Water for Injections should not be administered alone because it may cause hemolysis. Thecontraindications related to the added medicinal product should be considered.

4.4 Special warnings and precautions for use

Sterilized Water for Injections should not be administered alone because it may cause hemolysis. Thecontraindications related to the added medicinal product should be considered.

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 beconsidered.

4.6 Fertility, 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 hemolysis if administered alone.

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

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allowscontinued monitoring of the benefit/risk balance of the medicinal product.

4.9 Overdose

No effects are anticipated if used as instructed.

Hemolysis may occur following infusion of large volumes of hypotonic solutions using sterile water forinjections as diluent.

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

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeutic Group: Solvents and diluting agents, including irrigating solutions, ATC code:V07AB.

Sterilised Water for Injections being only the vehicle for the administration of the added medicinalproduct, the pharmacodynamics will depend on the nature of the drug added.

5.2 Pharmacokinetic properties

Sterilized Water for Injections being only the vehicle for the administration of the added medicinalproduct, the pharmacokinetics will depend on the nature of the drug added.

5.3 Preclinical safety data

Sterilized Water for Injections being only the vehicle for the administration of the added medicinalproduct, 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

Sterilized Water for Injections must not be mixed with other medicinal products unless their compatibilityhas been established.

6.3 Shelf life

- Unopened: Shelf life is 5 years.

- Opened: From a microbiological point of view, unless the method of opening / reconstitution / dilutionprecludes the risk of microbial contamination, the product should be used immediately.

If not used immediately, in-use storage times and conditions are the responsibility of the user.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

Pack sizes: 5 mL or 10 mL plastic ampoule.

6.6 Special precautions for disposal <and other handling>

For single use.

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

Keep out of sight and reach of children.

7. MARKETING AUTHORISATION HOLDER

Aculife Healthcare Pvt. Ltd.
Commerce House-V,
Beside Vodafone House
Prahladnagar Corporate Road,
Ahmedabad 380051,
Gujarat, India
Tel.: +91-79-26839100
E-mail: info@aculife.co.in

8. MARKETING AUTHORISATION NUMBER(S)

05718/07303/REN/2020

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28.03.2016

Date of latest renewal: 01.03.2021

10. DATE OF REVISION OF THE TEXT

Date: 12.07.2023