SUMMARY OF PRODUCT CHARACTERISTICS

1.3.1.1 Name of the finished pharmaceutical product

Sterilised Water For Injections BP

1.3.1.2 Qualitative and Quantitative composition

Composition:

Each ampoule contains: -

Sterilised Water for injections B.P..... 10 ml

1.3.1.3. Pharmaceutical form

Solvent for parenteral use.

A clear and colourless liquid.

1.3.1.4 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

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 special 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 FPPs 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.

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.

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.

1.3.1.5 Pharmacological properties

5.1 Pharmacodynamics properties

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

Water for Injections being only the vehicle for the administration of the added medicinal product, the pharmacodynamics will 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 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.

1.3.1.6 Pharmaceutical particulars

6.1 List of excipients

None

6.2 Incompatibilities

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

6.3 Shelf life

48 months from the date of manufacturing.

6.4 Special precautions for storage

Store at a temperature not exceeding 30°C.

Keep out of reach of children.

6.5 Nature and contents of container

Transparent 10mL FFS ampoules

Once bottle packed in carton with insert.

6.6 Instructions for use and handling and disposal

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

Amanta Healthcare Limited

Plot no: 876, N.H. No: 8, Hariyala, Kheda-387411, Gujarat, India.

8. Marketing authorization number(s)

04607/06881/REN/2018

9. Date of first authorization/renewal of the authorization

Sep 3, 2019

10. Date of revision of the text

Sep 3, 2019