Prescribing information (Summary of Product Characteristics)

1. Name of the Medicinal Product:

AXA AQUA (Sterile Water for Injection USP)

2. Qualitative and quantitative composition:

Qualitative Composition

Product Name: AXA AQUA

Generic Name: Sterile Water of Injection USP

Label Claim : Each ml contains:

Water for Injections USP.....q.s

3. Pharmaceutical form:

Solvent for parenteral use

Description: a clear colourless liquid

4. Clinical particulars:

4.1. Therapeutic indications:

Sterile 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:

Sterile Water for Injections should not be administered alone because it may cause hemolysis. 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 hemolysis.

4.5. Interaction with other finished pharmaceutical products and other forms of interactions:

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

4.6. Use during 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 allows continued monitoring of the benefit/risk balance of the medicinal product.

Healthcare professionals are asked to report any suspected adverse reactions.

4.9. Overdose (symptoms, emergency procedures, antidotes).

No effects are anticipated if used as instructed.

Hemolysis 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. Pharmacodynamics properties

Pharmacotherapeutic Group: Solvents and diluting agents
ATC code: V07AB.
Sterile 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

Sterile Water for Injection 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.

Sterile Water for Injection 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 Water for Injection USP

6.2. Incompatibilities.

Sterile Water for Injections must not be mixed with other medicinal products unless their compatibility has been established.

6.3. Shelf life

36 months

6.4. Special precautions for storage.

Store below 30^0C. Protect from light. Do not refrigerate or freeze.

6.5. Nature and contents of container.

10 ml in LDPE ampoule.

6.6. Instructions for use, handling and disposal:

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

7. Marketing authorisation holder.

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8. Marketing Authorization Number(s)

TAN 21 HM 0392

9. Date of the first authorisation/renewal of the authorisation.

2021-10-09

10. Date of revision of the text.