

MODULE-1	ADMINISTRATIVE INFORMATION AND PRODUCT INFORMATION
NAME OF THE PRODUCT	AXA AQUA (Sterile Water for Injection USP)

1.6 Product Information

1.6.1 Prescribing Information (Summary of Product Characteristics)

1. Name of the Medicinal Product:
AXA AQUA (Sterile Water for Injection USP)

1.1 Strength
q.s (10ml)

1.2 Pharmaceutical form
Solvent for parenteral use

2. Qualitative and Quantitative Composition:

2.1 Qualitative declaration
Product Name: AXA AQUA
Generic Name: Sterile Water for Injection USP
Label Claim: Each ml contains:
 Water for Injection USP.....q.s

2.2 Quantitative declaration

S. No.	Name of Ingredient	Reference	Qty. / ampoules	Batch Qty.
1.	Water for Injection	USP	10 mL	1050 Ltr

2.3 Salts and hydrates
 Each ml contains:
 Water for Injection USP.....q.s

3. Pharmaceutical Form
 Solvent for parenteral use



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4. Clinical Particulars**4.1 Therapeutic indications**

Sterile Water for Injection 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.

4.3 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.

4.5 Special warnings and precautions for use

Water for Injection is hypotonic and it should not be administered alone, because it may cause hemolysis.

4.6 Paediatric population

Not relevant

4.7 Interaction with other medicinal product and other forms of interaction

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

4.8 Additional information on special populations

Not relevant

4.9 Paediatric population

Not relevant

4.10 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.

4.11 Effects on ability to drive and use machines

Not relevant

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4.12 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.

4.13 Overdose

No effects are anticipated if used as instructed. Hemolysis may occur following infusion of large volumes of hypotonic solutions using sterile water for injection 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. Sterile Water for Injection 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.

6.0 Pharmaceutical particulars

6.1 List of Excipients

Water for Injection USP

6.2 Incompatibilities

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

6.3 Shelf life

36 months from the date of manufacturing.

6.4 Special precautions for storage

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

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- 6.5 Nature and contents of container**
48x10ml LDPE ampoules packed in a carton.
- 6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product**
For single use only any unused medicinal product or waste material should be disposed of in accordance with local requirements.
- 7. Marketing Authorization Holder**
Axa Parenterals Limited
Plot No 936, 937& 939
Vill. Kishanpur, Jamalpur, Roorkee-247667
Distt. Haridwar (Uttarakhand), INDIA.
Telephone: +91-1332-234041/42/43
Telefax: +91-1332-234040
E-Mail: axapar@axapar.com
- 8. Marketing Authorization Number(s)**
NA
- 9. Date of first authorization/renewal of the authorization**
NA
- 10. Date of revision of the text**
NA