SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT:

Water for Injections

Strength:
5 ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Sr. No.	Particulars	Grade	Qty./ml	Function
1	Water for Injection	BP	q.s. to 1 ml	Vehicle

3. PHARMACEUTICAL FORM:

Solvent for parenteral use

Clear, colourless, odourless, sterile solution intended for parenteral administration to human beings.

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 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 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 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 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.

5. PHARMACOLOGICAL PROPERTIES :

5.1 Pharmacodynamic properties:

Pharmacotherapeutic group (ATC code): 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 Pre-clinical 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:

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:

36 Months

6.4 Special precautions for storage:

Do not store above 25°C.

6.5 Nature and contents of container:

5ml flint, duly band snap off ampoule.

6.6 Special Precautions for 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 AUTHORIZATION HOLDER:

M/s. NEON LABORATORIES LIMITED

140, Damji Shamji Industrial Complex,
28, Mahal Indl. Estate, Mahakali Caves Road,
Andheri (East), Mumbai - 400 093

8. MARKETING AUTHORIZATION NUMBER:

05449/07191/REN/2019

9. DATE OF FIRST AUTHORIZATION / RENEWAL OF THE AUTHORISATION:

Date of first authorization: 04/11/2020

10. DATE OF REVISION OF THE TEXT:

JULY 2023

11. REFERENCE

- Water for Injections BP - Summary of Product Characteristics (SmPC) - (emc) Summary of Product Characteristics(SmPC)

  https://www.medicines.org.uk/emc/product/6624/smpc#gref