

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Water for Injections BP.

2.

QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1ml of solution contains 1ml of Water for Injections.

3. PHARMACEUTICAL FORM

Solution for Injection.

Clear, colourless, odourless, sterile solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Water for Injections is indicated to serve as a vehicle for dilution and reconstitution of suitable medicinal products for parenteral administration.

4.2 Posology and method of administration

Dosage:

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.

Administration:

For parenteral use. The directions for use related to the added medicinal product will dictate the appropriate volumes as well as the administration route.

4.3 Contraindications

None known.

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

None known.

4.6 Pregnancy and lactation

May be used during pregnancy and lactation.
The risks during use in pregnancy and in lactating women are determined by the nature of the added medicinal products.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

None known.
The nature of the additive will determine the likelihood of any undesirable effects.

4.9. Overdose

No effects anticipated with the proposed use.
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

Not applicable.
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

Not applicable.

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

No relevant information other than that which is included in other sections of the Summary of Product Characteristics.

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

Not applicable.

6.2. Incompatibilities

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

6.3. Shelf life

2 years.

Use immediately after first opening of the ampoule. Discard unused contents.

6.4. Special precautions for storage

Do not store above 25°C.

6.5. Nature and contents of container

5 ml or 10 ml hermetically sealed translucent plastic ampoules, polyethylene Ph. Eur. packed in cardboard cartons to contain 10 or 100 ampoules.

6.6. Special precautions for disposal

For parenteral use.

Use as directed by a medical practitioner.

If only part of the ampoule is used, discard the remaining solution.
Keep out of the reach and sight of children.

7. MARKETING AUTHORISATION HOLDER

Antigen International Ltd
Roscrea
County Tipperary
Ireland.

8. MARKETING AUTHORISATION NUMBER

PL 02848/0228

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

31/08/2007

10 DATE OF REVISION OF THE TEXT

31/08/2007