

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Water for Injections B.P.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

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

For the reconstitution, dilution and making-up of appropriate drugs where Water for Injections is the diluent of choice, and for use as an irrigant.

4.2. Posology and Method of Administration

Route of administration: As appropriate to the reconstituted drug.

Dosage: In accordance with the particular situation for which Water for Injections B.P. is being used.

4.3. Contra-Indications

None known.

4.4. Special Warnings and Special Precautions for Use

None.

4.5. Interactions with other Medicinal Products and other Forms of Interaction

None known.

4.6. Pregnancy and Lactation

May be used during this period.

4.7. Effects on Ability to Drive and Use Machines

None.

4.8. Undesirable Effects

None known.

4.9. Overdose

No effects anticipated with the proposed use.

5. Pharmacological Properties

5.1. Pharmacodynamic Properties

Not applicable.

5.2. Pharmacokinetic Properties

Not applicable.

5.3. Pre-clinical Safety Data

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

6. Pharmaceutical Particulars

6.1. List of Excipients

Not applicable.

6.2. Incompatibilities

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

6.3. Shelf Life

3 years.

6.4. Special Precautions for Storage

Do not store above 25°C.

6.5. Nature and Content of Container

2ml, 5ml and 10ml hermetically sealed translucent plastic ampoules, polypropylene Ph.Eur., packed in cardboard cartons to contain 10, 20, 50 and 100 ampoules.

6.6. Instructions for Use, Handling and Disposal

As appropriate to the reconstituted drug.

If only part of an ampoule is used, discard the remaining solution.

Use as directed by the physician.

Keep out of reach of children

7. MARKETING AUTHORISATION HOLDER

Antigen International Ltd.,
Roscrea,
County Tipperary,
Ireland.

8. MARKETING AUTHORISATION NUMBER

PL 2848/0152.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

Date of first authorization: 10/10/91.

10. DATE OF (PARTIAL) REVISION OF THE TEXT

26/08/2009