

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Water for Injections BP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Water for Injections BP

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 BP is being used.

4.3 Contra-indications

None known.

4.4 Special warnings and special precautions for use

None known.

4.5 Interaction 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 known.

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

6.3 Shelf life

5 years (60 months).

If only part of the contents of an ampoule is used, the remaining solution should be discarded.

6.4 Special precautions for storage

Keep the container in the outer carton in order to protect from light.

Do not store above 25°C.

6.5 Nature and contents of container

2ml, 5ml and 10ml clear One point cut (OPC) glass ampoules, glass, type 1 Ph. Eur. borosilicate glass packed in cardboard cartons to contain 10 ampoules.

6.6 Instructions for use/handling

Not applicable.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

PL 02848/5924R.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first PL : 26 September 1986

Date of last renewal : 08 February 1999

10. DATE OF (PARTIAL) REVISION OF TEXT

June 2009