



SUMMARY OF PRODUCT CHARACTERISTICS

PRODUCT SUMMARY

1. NAME OF THE MEDICINAL PRODUCT

Water for Injections BP 50ml and 100ml vials.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Water for Injections BP/Ph. Eur. 50ml and 100ml.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear, colourless, odourless, sterile solution.

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. 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 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

None.

6.3. Shelf life

5 years (60 months).

6.4. Special precautions for storage

Protect from light.

Store below 25°C.

6.5. Nature and contents of container

50ml and 100ml clear glass vials, type 1 Ph. Eur. with rubber bungs.

6.6. Instructions for use and handling

Not applicable.

ADMINISTRATION DETAILS

7. MARKETING AUTHORISATION HOLDER

Antigen International Ltd.
Roscrea
Co. Tipperary
Ireland

8. MARKETING AUTHORISATION NUMBER

PL 02848/0010

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

22 March 1973 / 12 November 1998

10. DATE OF (PARTIAL) REVISION OF THE TEXT

May 2003.