

Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

Water for Injections BP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Water for Injections 100% v/v

3. PHARMACEUTICAL FORM

Solvent for parenteral use.

A clear, colourless, odourless and tasteless sterile liquid.

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 Contraindications

None known.

4.4 Special warnings and 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

None

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf Life

5 years

6.4 Special precautions for storage

Do not store above 25°C.
Keep the ampoule in the outer carton in order to protect from light.

6.5 Nature and contents of container

2 ml, 5 ml and 10 ml clear glass ampoules, glass type I Ph. Eur. borosilicate glass, packed in cardboard cartons to contain 10 ampoules.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal of used medicinal product or waste materials derived from such medicinal product and other handling of the product

After single use, any remaining solvent should be discarded.

7. MARKETING AUTHORISATION HOLDER

Antigen Pharmaceuticals Limited
Chandler House
Castle Street
Roscrea
County Tipperary
Ireland

8. MARKETING AUTHORISATION NUMBER

PA 0073/107/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 03 June 1988

Date of last renewal: 3rd June 2008

10. DATE OF REVISION OF THE TEXT

May 2009