

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Water for Injections Ph. Eur.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains the stated amount (i.e., 5, 10, 15, 20, 25, 30, 50, 100, 192 or 200ml) of Water for Injections Ph. Eur.

3 PHARMACEUTICAL FORM

Solvent for parenteral use.

Type I Ph. Eur. glass vial sealed by a rubber stopper with a green plastic flip-off cap.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For use as a diluent for reconstitution of injectable products.

4.2 Posology and method of administration

Use as appropriate for the injectable product being dissolved.

4.3 Contraindications

None known.

4.4 Special warnings and precautions for use

Render isotonic prior to intravenous administration. Discontinue administration if adverse reaction occurs.

4.5 Interaction with other medicinal products and other forms of interaction

Not applicable.

4.6 Pregnancy and lactation

Not applicable.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Not applicable.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not applicable.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Not applicable.

6.2 Incompatibilities

Additives should not be used unless compatibility is known.

6.3 Shelf Life

Five years.

6.4 Special precautions for storage

Store below 25°C. Do not freeze.

6.5 Nature and contents of container

Clear sterile solution supplied in volumes of 5, 10, 15, 20, 25, 30, 50, 100, 192 or 200 ml in Type I Ph. Eur. glass vials sealed by a rubber stopper with a green plastic flip-off cap.

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

Do not use unless contents are clear and the container is undamaged. Do not vent.

7 MARKETING AUTHORISATION HOLDER

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Norfolk IP24 1HZ
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8 MARKETING AUTHORISATION NUMBER

PA 0415/008/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17 December 1992

Date of last renewal: 17 December 1997

10 DATE OF REVISION OF THE TEXT

September 1997