

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Water for Injections 100 % w/v, 3 ml Vial

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Not applicable.

For excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solvent for parenteral use. Solution for the reconstitution of lyophilized vaccine preparations.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For reconstitution of lyophilized vaccines.

4.2 Posology and method of administration

Subcutaneous or intramuscular injection.

4.3 Contraindications

As for the product to be reconstituted.

4.4 Special warnings and precautions for use

As for the product to be reconstituted.

4.5 Interaction with other medicinal products and other forms of interaction

As for the product to be reconstituted.

4.6 Pregnancy and lactation

As for the product to be reconstituted.

4.7 Effects on ability to drive and use machines

As for the product to be reconstituted.

4.8 Undesirable effects

As for the product to be reconstituted.

4.9 Overdose

As for the product to be reconstituted.

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

Water for Injections.

6.2 Incompatibilities

As for the product to be reconstituted.

6.3 Shelf Life

5 years.

6.4 Special precautions for storage

Keep the ampoules in the outer carton. Store between 2 °C and 8 °C. Do not freeze.

6.5 Nature and contents of container

3ml Type I, Ph. Eur. clear glass single dose vials with rubber closures and aluminium over caps. (The Water for Injection is supplied in a carton for reconstitution with the appropriate vaccine).

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

As for the product to be reconstituted. Discard any unused contents. For single use only.

7 MARKETING AUTHORISATION HOLDER

GlaxoSmithKline (Ireland) Limited
Stonemasons Way
Rathfarnham
Dublin 16

8 MARKETING AUTHORISATION NUMBER

PA 1077/39/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 07 September 1999

Date of last renewal: 07 September 2004

10 DATE OF REVISION OF THE TEXT

October 2005