Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sterile Saline Solution (0.9 % w/v), 1 ml ampoule

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Not applicable.

For excipients, see section 6.1.

3 PHARMACEUTICAL FORM

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

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For reconstitution of lyophilised 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

Sodium chloride
Water for Injection

6.2 Incompatibilities

As for the product to be reconstituted.

6.3 Shelf Life

5 years.

6.4 Special precautions for storage

Keep the syringe in the outer carton. Store between 2 ºC and 8 ºC. Do not freeze.

6.5 Nature and contents of container

Type I Ph. Eur. 1ml single dose syringes with or without needles, fitted with rubber stoppers containing 0.5ml diluent. The stoppers are attached to a polypropylene or polystyrene plunger. (The sterile Saline Soluion is supplied in a carton with the appropriate vaccine for reconstitution).

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
Ireland

8 MARKETING AUTHORISATION NUMBER

PA 1077/31/3

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7 September 1999

Date of last renewal: 7 September 2004

10 DATE OF REVISION OF THE TEXT

November 2005