SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Italy: Porsilis Strepsuis
Spain, Portugal, Greece: Porcilis Strepsuis

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of two ml:

Active substance(s):
- *Streptococcus suis* serotype 2 strain P 1/7: inducing ≥ 9.2 and ≤ 15.0 $\log_2$ Ab titre[1]

[1] Mean antibody titre (Ab) obtained after vaccination of chickens with a 1/4 pig dose.

Adjuvant(s):
150 mg dl-α-tocopheryl acetate

Excipient(s):
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection

4. CLINICAL PARTICULARS

4.1 Target species

Pigs (piglets, breeding pigs)

4.2 Indications for use, specifying the target species

For passive immunization of the progeny of vaccinated sows and gilts to reduce mortality and clinical signs due to *Streptococcus suis* serotype 2 infection.
The duration of passive immunity is 3 weeks provided that the piglets received sufficient colostrum at the first day after birth.

OR

For active immunization of pigs (piglets from the age of 2 weeks) to reduce mortality and clinical signs due to Streptococcus suis serotype 2 infection.
The onset of immunity: 1 week after the second vaccination.
The duration of immunity: at least two weeks.

4.3 Contraindications

None known

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals

None

Special precautions to be taken by the person administering the veterinary medicinal product to animals

In the case of accidental injection/self-injection, seek medical advice immediately and show the package insert or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

A local transient swelling at the site of injection may occur. A tendency of some pigs to lie down and a mild transient temperature increase may occur, but pigs are completely recovered the next day

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy

4.8 Interaction with other medicinal products and forms of interaction

No information is available on the safety and efficacy from the concurrent use of this vaccine with any other. It is therefore recommended that no other vaccines should be administered within 14 days before and after vaccination with the product.

4.9 Amounts to be administered and administration route

Administer a dose of 2 ml intramuscularly in the neck of the pig.
Allow vaccine to reach ambient temperature.
Shake well before use.

Vaccination scheme:

- Piglets (from non-vaccinated sows):
Two injections with an interval of three weeks, in piglets from two weeks of age.

OR

- Sows and gilts:
Basic vaccination: Sows and gilts which have not been vaccinated with the product shall be given a primary injection 6-8 weeks before the expected date of farrowing and a booster injection four weeks later.
Re-vaccination: a single re-vaccination shall be given 2-4 weeks prior to the expected date of each next farrowing.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No abnormal local reaction or systemic reactions after vaccination with a double overdose.

4.11 Withdrawal period(s)

Zero days

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: inactivated bacterial vaccine. ATC vet code: QI09AB.
Vaccine to stimulate active immunity against *Streptococcus suis* serotype 2 or to stimulate active immunity in order to provide passive immunity to the progeny against *Streptococcus suis* serotype 2.

The immunogens are incorporated in a dl-α-tocopheryl acetate based adjuvant to enhance a prolonged stimulation of immunity. Progeny of vaccinated sows and gilts derive a passive immunity via the colostrum.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polysorbate 80, Simethicone, Sodium chloride, KH_2PO_4, $Na_2HPO_42H_2O$, water for injections

6.2 incompatibilities

Do not mix with any other vaccine/immunological product.

6.3 Shelf life

2 years
Use broached vials immediately after opening

6.4 Special precautions for storage

Store at 2°C - 8°C. Do not freeze.

6.5 Nature and composition of immediate packaging

20 ml (10 dose presentation), 50 ml (25 dose presentation) or 100 ml (50 dose presentation) vials of PET or glass Type I (Ph. Eur.) closed with a halogenobutyl rubber stopper and sealed with coded aluminium cap.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused product or waste material should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

Intervet International
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Represented by the national company.

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT

6 April 2006

PROHIBITION OF SALE, SUPPLY AND/OR USE