SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porsilis Strepsuis suspension for injection for pigs (IT)
Porcilis Strepsuis suspension for injection for pigs (EL, ES, PT)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose contains:

Active substances:
Streptococcus suis serotype 2 strain P 1/7, inactivated: 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.

Adjuvants:
dl-α-tocopheryl acetate 150 mg

Excipients:

Qualitative composition of excipients and other constituents
Polysorbate 80
Simethicone
Sodium chloride
Potassium dihydrogen phosphate
Disodium phosphate dihydrate
Water for injections

Aqueous, white, or nearly white suspension.

3. CLINICAL INFORMATION

3.1 Target species

Pig (piglet, sow for reproduction)

Eliminato: s
Eliminato: sows and gilts

3.2 Indications for use for each 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.
Onset of immunity: at birth.
Duration of immunity: 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.

Onset of immunity: 1 week after the second vaccination.
Duration of immunity: at least 2 weeks.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

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

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

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pig (piglet, sow for reproduction):

Very common (>1 animal / 10 animals treated):	Elevated temperature[1,2], Lying down[1]; Injection site swelling

[1] Pigs are completely recovered the next day.
[2] Mild.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Can be used during pregnancy.

3.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case-by-case basis.

3.9 Administration routes and dosage

Intramuscular use.
Administer one dose of 2 ml per animal by intramuscular injection 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI09AB.

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Do not freeze.

5.4 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 bromobutyl rubber stopper and sealed with coded aluminium cap.

Pack sizes:
Cardboard box with 1 vial (PET or glass Type I) of vaccine containing 20 ml (10 dose presentation), 50 ml (25 dose presentation) or 100 ml (50 dose presentation).

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}.

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porsilis Strepsuis suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each 2 ml dose contains:
Streptococcus suis serotype 2 strain P 1/7, inactivated: ≥ 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.

3. PACKAGE SIZE

20 ml (10 doses)
50 ml (25 doses)
100 ml (50 doses)

4. TARGET SPECIES

Pig (piglet, sow for reproduction)

Eliminato: s
Eliminato: sows and gilts

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal periods: zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not freeze.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vials of PET or glass (100 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porsilis Strepsuis suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each 2 ml dose contains:
S. suis serotype 2: ≥ 9.2 and ≤ 15.0 $\log_2$ Ab titre

50 doses

3. TARGET SPECIES

Pig (piglet, sow for reproduction)

Eliminato: s

Eliminato: sows and gilts

4. ROUTES OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods: zero days.

Eliminato: Z

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use immediately.

7. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator. Do not freeze.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

9. BATCH NUMBER

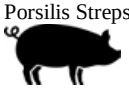
Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vials of PET or Glass (20 ml or 50 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porsilis Strepsuis



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each 2 ml dose contains:
S. suis serotype 2: ≥ 9.2 and ≤ 15.0 $\log_2$ Ab titre

10 doses
25 doses

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use immediately.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Porsilis Strepsuis suspension for injection for pigs

2. Composition

Each 2 ml dose contains:

Active substances:
Streptococcus suis serotype 2 strain P 1/7, inactivated: 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.

Adjuvants:
dl-α-tocopheryl acetate 150 mg

Aqueous, white, or nearly white suspension.

3. Target species

Pig (piglet, sow for reproduction)

4. Indications for use

For passive immunization of the progeny of vaccinated sows and gilts to reduce mortality and clinical signs due to *Streptococcus suis* serotype 2 infection.
Onset of immunity: at birth.
Duration of immunity: 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.
Onset of immunity: 1 week after the second vaccination.
Duration of immunity: at least 2 weeks.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

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

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

Pregnancy:
Can be used during pregnancy.

Interaction with other medicinal products and other forms of interaction:
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case-by-case basis.

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

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Pig (piglet, sow for reproduction):

Very common (>1 animal / 10 animals treated):	Elevated temperature[1,2], Lying down[1]; Injection site swelling

[1] Pigs are completely recovered the next day.
[2] Mild.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system:

8. Dosage for each species, routes and method of administration

Intramuscular use.
Administer one dose of 2 ml per animal by intramuscular injection in the neck of the pig.

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 followed by 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.

9. Advice on correct administration

Use sterile vaccination equipment.
Allow the vaccine to reach ambient temperature and shake well before use.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store in a refrigerator (2 °C – 8 °C).
Do not freeze.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: use immediately.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Pack sizes:
Carboard box with 1 vial containing 20 ml (10 doses), 50 ml (25 doses) or 100 ml (50 doses).
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder , and manufacturer responsible for batch release and contact details to report suspected adverse events:

Manufacturer responsible for batch release:
Intervet International B.V., Wim de Körverstraat 35, 5831 AN Boxmeer, The Netherlands

Local representatives and contact details to report suspected adverse events:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

The antigen is 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.

Any additional information concerning distribution, possession or any necessary precaution in conformity with the marketing authorisation and in accordance with article 14(2) and/or national requirements may appear in this rectangle boxed area