SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Ery+Parvo suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose contains:

Active substances:
Erysipelothrix rhusiopathiae, serotype 2, strain M2, inactivated ≥ 1 ppd*
Porcine Parvovirus, strain 014, inactivated ≥ 552 EU**
*ppd = pig protective dose as compared to a reference preparation known to be protective in pigs.
**EU = as determined in the final product by antigenic mass ELISA.

Adjuvant:
dl-α-tocopherol: 150 mg

Excipients:

Qualitative composition of excipients and other constituents
Polysorbate 80
Tris (hydroxymethyl) aminomethane
Sodium chloride
Simethicone
Hydrochloric acid
Water for injections

Homogenous white to nearly white suspension after shaking.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (sows and gilts).

3.2 Indications for use for each target species

For active immunisation of sows and gilts to prevent clinical signs of Erysipelas disease caused by all relevant *Erysipelothrix (E.) rhusiopathiae* serotypes (serotype 1 and 2) and for protection against embryonal and fetal death caused by porcine parvovirus (PPV) infection.

E. rhusiopathiae:
Onset of immunity (after finished primary vaccination course): 3 weeks.
Duration of immunity: 6 months.

Porcine parvovirus:
Onset of immunity: has not been established.
Duration of immunity: 12 months.

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 label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pigs (sows and gilts):

Very common (>1 animal / 10 animals treated):	Elevated temperature[1]; Injection site swelling[2].
Common (1 to 10 animals / 100 animals treated):	Reluctant to move[3].
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction.

[1] Transient increase (+0.5 °C) within 24 hours after vaccination.
[2] Mild transient local swelling (Ø 1-10 mm) until 8 days after vaccination.
[3] Transient reaction.

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.
[< > to be adjusted nationally]

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy and lactation.

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

Administer one dose of 2 ml by deep intramuscular injection behind the ear.

Before use, allow the vaccine to reach room temperature. Shake well before use.
Use sterile syringe and needles. Avoid introduction of contamination by multiple broaching.

Primary vaccination course:
Protection against *E. rhusiopathiae* and PPV should be achieved in gilts before first mating. A single injection not later than 2 weeks before mating is sufficient to protect the following pregnancy from damage due to PPV. For the induction of protection against Erysipelas a double vaccination as a basic vaccination is advised. This can be achieved with the single Erysipelas vaccine either 4 weeks before or 4 weeks after the application of the combined ERY-PARVO vaccine.
Due to possible interference with maternal antibodies the pigs should have reached the age of 6 months before vaccination to ensure efficacy against porcine parvovirus.

Revaccinations should be given once a year, supplemented with the administration of a single Erysipelas vaccine, 6 months post each Porcilis Ery+Parvo vaccination.

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

Reactions observed after administration of a double dose are not different from those observed after administration of a single dose.

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.
[to be completed nationally]

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI09AL01.

For the active immunisation of sows and gilts, as an aid in the control of swine erysipelas and for the protection of their embryos and fetuses against porcine parvovirus infection.
The antigens are incorporated in an aqueous tocopherol-based adjuvant in order to enhance a prolonged stimulation of immunity.

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: 10 hours.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

PET (polyethylene terephthalate)-vial closed with a halogenobutyl rubber stopper and sealed with a coded aluminium cap.

Package sizes:
Carboard box with 1 vial of 20 ml (10 doses).
Carboard box with 1 vial of 50 ml (25 doses).
Carboard box with 1 vial of 100 ml (50 doses).
Carboard box with 1 vial of 250 ml (125 doses).

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater <or household waste>.
[< > to be adjusted nationally]
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

[to be completed nationally]

7. MARKETING AUTHORISATION NUMBER(S)

[to be completed nationally]

8. DATE OF FIRST AUTHORISATION

Date of first authorization: {DD/MM/YYYY}.
[to be completed nationally]

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

{MM/YYYY}
[to be completed nationally]

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).

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Ery+Parvo suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each 2 ml dose contains:

Erysipelothrix rhusiopathiae, serotype 2, strain M2, inactivated:	≥ 1 pig protective dose
Porcine Parvovirus, strain 014, inactivated:	≥ 552 EU

3. PACKAGE SIZE

20 ml (10 doses)
50 ml (25 doses)
100 ml (50 doses)
250 ml (125 doses)

4. TARGET SPECIES

Pigs (sows and gilts).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 10 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not freeze.
Protect from light.

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

[to be completed nationally]

14. MARKETING AUTHORISATION NUMBERS

[to be completed nationally]

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

PET vials of 100/250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Ery+Parvo suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each 2 ml dose contains:
Erysipelothrix rhusiopathiae, strain M2, inactivated: ≥ 1 ppd
Porcine parvovirus, strain 014, inactivated: ≥ 552 EU

100 ml (50 doses)
250 ml (125 doses)

3. TARGET SPECIES

Pigs (sows and gilts)

4. ROUTES OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 10 hours.

7. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not freeze.
Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

[to be completed nationally]

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

PET vials of 20/50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Ery+Parvo

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

E. rhusiopathiae, strain M2, inactivated: ≥ 1 ppd
PPV, strain 014, inactivated: ≥ 552 EU

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

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 10 hours.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Porcilis Ery+Parvo suspension for injection for pigs

2. Composition

Each 2 ml dose contains:

Active substances:
Erysipelothrix rhusiopathiae, strain M2, inactivated: ≥ 1 ppd
Porcine parvovirus, strain 014, inactivated: ≥ 552 EU
* ppd = pig protective dose as compared to a reference preparation known to be protective in pigs.
** EU = as determined in the final product by antigenic mass ELISA.

Adjuvant:
dl-α-tocopherol: 150 mg

Homogenous white to nearly white suspension after shaking.

3. Target species

Pigs (sows and gilts).

4. Indications for use

For active immunisation of sows and gilts to prevent clinical signs of Erysipelas disease caused by all relevant *Erysipelothrix (E.) rhusiopathiae* serotypes (serotype 1 and 2) and for protection against embryonal and fetal death caused by porcine parvovirus (PPV) infection.

E. rhusiopathiae:
Onset of immunity (after finished primary vaccination course): 3 weeks.
Duration of immunity: 6 months.

PPV:
Onset of immunity: has not been established.
Duration of immunity: 12 months.

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 label to the physician.

Pregnancy and lactation:
Can be used during pregnancy and lactation.

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:
Reactions observed after administration of a double dose are not different from those observed after administration of a single dose.

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

7. Adverse events

Pigs (sows and gilts):

Very common (>1 animal / 10 animals treated):	Elevated temperature[1]; Injection site swelling[2].
Common (1 to 10 animals / 100 animals treated):	Reluctant to move[3].
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction.

[1] Transient increase (+0.5 °C) within 24 hours after vaccination.
[2] Mild transient local swelling (Ø 1-10 mm) until 8 days after vaccination.
[3] Transient reaction.

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 the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

[< > to be adjusted nationally]

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

Administer one dose of 2 ml by deep intramuscular injection behind the ear.

Primary vaccination course:
Protection against *E. rhusiopathiae* and PPV should be achieved in gilts before first mating. A single injection not later than 2 weeks before mating is sufficient to protect the following pregnancy from damage due to PPV. For the induction of protection against Erysipelas a double vaccination as a basic vaccination is advised. This can be achieved with the single Erysipelas vaccine either 4 weeks before or 4 weeks after the application of the combined ERY-PARVO vaccine.
Due to possible interference with maternal antibodies the pigs should have reached the age of 6 months before vaccination to ensure efficacy against porcine parvovirus.

Revaccinations should be given once a year, supplemented with the administration of a single Erysipelas vaccine, 6 months post each Porcilis Ery+Parvo vaccination.

9. Advice on correct administration

Before use, allow the vaccine to reach room temperature. Shake well before and regularly during use. Use sterile vaccination equipment. Avoid introduction of contamination by multiple broaching.

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.
Protect from light.

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: 10 hours.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater <or household waste>.
[< > to be adjusted nationally]
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.
[< > to be adjusted nationally]

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

[to be completed nationally]

Pack sizes:
Cardboard box with one vial of 20 ml (10 doses), 50 ml (25 doses), 100 ml (50 doses) or 250 ml (125 doses).
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY} [to be completed nationally]

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 reactions>:
[< > to be adjusted nationally]

<Manufacturer responsible for batch release:> [to be adjusted nationally if included in the above]
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

<Local representative < and contact details to report suspected adverse reactions>:>
[< > to be adjusted nationally]

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.>
[< > to be adjusted nationally]

17. Other information

For the active immunisation of sows and gilts as an aid in the control of swine erysipelas and for the protection of their embryos and fetuses against porcine parvovirus infection. The active substances are inactivated strains of *E. rhusiopathiae*, serotype 2 (strain M2) and PPV strain 014.
The antigens are incorporated in an aqueous tocopherol-based adjuvant in order to enhance a prolonged stimulation of immunity.
[to be completed nationally]