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 dose (2 ml) contains:

Active substances:
Inactivated strains of:

Erysipelothrix rhusiopathiae, serotype 2 (strain M2)	≥ 1 ppd*
Porcine Parvovirus (strain 014)	≥ 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:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
Homogenous white to nearly white suspension after shaking.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs (Sows and Gilts).

4.2 Indications for use, specifying the target species

For active immunization 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:
Duration of immunity: 12 months

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals
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.

4.6 Adverse reactions (frequency and seriousness)

In laboratory studies and field trials:
Transient increases in body temperature (0.5°C) within 24 hours may very commonly occur. Mild transient local swelling (Ø 1-10mm) until 8 days after vaccination may very commonly occur. Transient reluctance to move may commonly occur.

In post marketing experience:
In very rare cases, a hypersensitivity reaction may occur.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

4.8 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.

4.9 Amounts to be administered and administration route

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.

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

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

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated bacterial and inactivated viral vaccines
ATCvet code: QI09AL01

The active substances are a lysate of *E. rhusiopathiae* strain M2 (serotype 2) and inactivated porcine parvo virus strain 014.
For the active immunization 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polysorbate 80
Tris (hydroxymethyl) aminomethane
Sodium chloride
Simethicone
Hydrochloric acid
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 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

6.4. Special precautions for storage

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

6.5 Nature and composition of immediate packaging

PET-vial closed with a halogenobutyl rubber stopper and sealed with a coded aluminium cap.

Package sizes:
1 vial of 20 ml (10 doses), 50 ml (25 doses), 100 ml (50 doses) or 250 ml (125 doses) packed in a cardboard box.
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 veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Intervet International B.V., as represented by the national company
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT

09/2022

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Ery+Parvo suspension for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Inactivated strains of:
Erysipelothrix rhusiopathiae, serotype 2 (strain M2): ≥ 1 pig protective dose
Porcine Parvovirus (strain 014): ≥ 552 EU

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

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

5. TARGET SPECIES

Pigs (Sows and Gilts)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Intramuscular use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous.
Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

[*To be completed nationally*]

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vials of 100/250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Ery+Parvo suspension for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Inactivated *E. rhusiopathiae*, (strain M2): ≥ 1 ppd
Inactivated PPV strain 014: ≥ 552 EU

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

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

5. TARGET SPECIES

Pigs (Sows and Gilts)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Intramuscular use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous.
Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

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

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

[*To be completed nationally*]

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

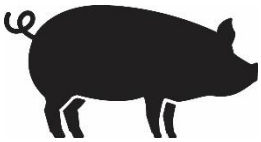
Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vials of 20/50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Ery+Parvo



2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Inactivated *E. rhusiopathiae*, (strain M2): ≥ 1 ppd
Inactivated PPV strain 014: ≥ 552 EU

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

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

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once broached use within 10 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Porcilis Ery+Parvo Suspension for injection for pigs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
The national representative of
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Ery+Parvo suspension for injection for pigs

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each dose (2 ml) contains:

Active substances:
Inactivated strains of:
- *Erysipelothrix rhusiopathiae,* serotype 2 (strain M2): ≥ 1 ppd*
- Porcine Parvovirus (strain 014): ≥ 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

Suspension for injection.
Homogenous white to nearly white suspension after shaking.

4. INDICATION

For active immunization 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:
Duration of immunity: 12 months

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

In laboratory studies and field trials:
Transient increases in body temperature (0.5°C) within 24 hours may very commonly occur.
Mild transient local swelling (Ø 1-10mm) until 8 days after vaccination may very commonly occur.
Transient reluctance to move may commonly occur.

In post marketing experience:
In very rare cases, a hypersensitivity reaction may occur.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any serious effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs (Sows and Gilts).

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 PERIOD(S)

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 after the expiry date stated on the label.
Shelf life after first opening the container: 10 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.

Special precautions for use in animals:
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.

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 (symptoms, emergency procedures, antidotes):
Reactions observed after administration of a double dose are not different from those observed after administration of a single dose.

Interactions:
Do not mix with any other veterinary medicinal product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

For the active immunization 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.

Cardboard box with one vial of 20, 50, 100 or 250 ml.

Not all pack sizes may be marketed.