

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Ery+Parvo+Lepto suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose contains:

Active substances:

Inactivated strains of:

<i>Erysipelothrix rhusiopathiae</i> , serotype 2 (strain M2)	≥ 1 ppd ¹
Porcine parvovirus (strain 014)	≥ 130 U ²
<i>Leptospira interrogans</i> serogroup Canicola serovar Portland-Vere (strain Ca-12-000)	≥ 2816 U ²
<i>Leptospira interrogans</i> serogroup Icterohaemorrhagiae serovar Copenhageni (strain Ic-02-001)	≥ 210 U ²
<i>Leptospira interrogans</i> serogroup Australis serovar Bratislava (strain As-05-073)	≥ 1310 U ²
<i>Leptospira kirschneri</i> serogroup Grippotyphosa serovar Dadas (strain Gr-01-005)	≥ 648 U ²
<i>Leptospira interrogans</i> serogroup Pomona serovar Pomona (strain Po-01-000)	≥ 166 U ²
<i>Leptospira santarosai</i> serogroup Tarassovi serovar Gatuni (strain S1148/02)	≥ 276 U ²

Adjuvant:

dl- α -tocopheryl acetate 150 mg

¹ Pig protective dose as compared to a reference preparation known to be protective in pigs.

² As determined in the *in vitro* antigenic mass ELISA potency test.

Excipients:

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

Homogenous white to nearly white suspension after shaking.

3. CLINICAL INFORMATION

3.1 Target species

Pigs for reproduction.

3.2 Indications for use for each target species

For the active immunisation of pigs:

-to reduce clinical signs (skin lesions and fever) of swine erysipelas caused by *Erysipelothrix rhusiopathiae*, serotype 1 and serotype 2.

-to reduce transplacental infection, viral load and fetal mortality caused by Porcine parvovirus.

-to reduce clinical signs (increase of body temperature and reduction in feed intake or activity), infection and bacterial excretion caused by *L. interrogans* serogroup Canicola serovar Canicola.
-to reduce clinical signs (increase of body temperature and reduction in feed intake or activity), severity of infection and foetal mortality caused by *L. interrogans* serogroup Pomona serovar Pomona.
-to reduce infection caused by *L. interrogans* serogroup Icterohaemorrhagiae serovars Copenhageni and Icterohaemorrhagiae, *L. interrogans* serogroup Australis serovar Bratislava, *L. kirschneri* serogroup Grippotyphosa serovars Grippotyphosa and Bananal/Liangguang, *L. weilii* serogroup Tarassovi serovar Vughia and *L. borgpetersenii* serogroup Tarassovi serovar Tarassovi.

Onset of immunity:

E. rhusiopathiae: 3 weeks

Porcine parvovirus: 10 weeks

Leptospira serogroups: 2 weeks

Duration of immunity:

E. rhusiopathiae: 6 months

Porcine parvovirus: 1 year

Leptospira serogroup Australis: 6 months

Leptospira serogroups Canicola, Icterohaemorrhagiae, Grippotyphosa, Pomona and Tarassovi: 1 year

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

Pigs for reproduction:

Very common (>1 animal / 10 animals treated):	Elevated temperature ¹ Injection site swelling ²
Uncommon (1 to 10 animals / 1,000 animals treated):	Decreased activity ³ , reduced food intake ³
Rare (1 to 10 animals / 10,000 animals treated):	Vomiting ⁴ , reddening of the skin ⁴ , tachypnoea ⁴ , twitching ⁴
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction

¹ The observed mean increase was 0.5 °C (in individual cases the maximum increase was 1.5 °C) up until 2 days after vaccination.

² Local reactions, mostly consisting of red, mild to hard, non-painful swellings. In general, local reactions may have a diameter of ≤ 5 cm, and in very rare cases local reactions in individual animals can be up to 20 cm in diameter. All local reactions disappear completely within approximately 2 weeks after vaccination.

³ Feed intake and activity are completely restored within a week.

⁴ Intermediate systemic reactions, which resolve in a few minutes.

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 section “Contact details” of the package leaflet.

[<> 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

Before use allow the vaccine to reach room temperature.

Shake well before use.

Avoid introduction of contamination by multiple broaching.

For intramuscular use.

Administer a single dose of 2 ml in the neck region.

Basic vaccination scheme: Pigs which have not yet been vaccinated shall be given a primary injection 6 to 8 weeks before the expected date of insemination and a booster injection 4 weeks later.

Revaccination: A single revaccination with the veterinary medicinal product should be given once a year. Six months post each vaccination with the veterinary medicinal product, a single revaccination with an *Erysipelothrix rhusiopathiae* containing product should be given to maintain immunity against *Erysipelothrix rhusiopathiae*. In case of known infection pressure with *L. interrogans* serogroup Australis, a single revaccination with the veterinary medicinal product should be given every six

months, as it is unknown if or for how long the duration of immunity for this serogroup persists beyond six months.

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

No adverse events other than those mentioned in section 3.6 were observed after the administration of a double dose of vaccine.

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 : QI09AL07.

The veterinary medicinal product stimulates the development of active immunity in pigs against *E. rhusiopathiae*, Porcine parvovirus, *L. interrogans* serogroup Canicola serovar Canicola, *L. interrogans* serogroup Icterohaemorrhagiae serovars Copenhageni and Icterohaemorrhagiae, *L. interrogans* serogroup Australis serovar Bratislava, *L. kirschneri* serogroup Grippytyphosa serovars Grippytyphosa and Bananal/Liangguang, *L. interrogans* serogroup Pomona serovar Pomona, *L. weilii* serogroup Tarassovi serovar Vughia and *L. borgpetersenii* serogroup Tarassovi serovar Tarassovi.

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 vials of 20 ml (10 doses), 50 ml (25 doses), 100 ml (50 doses) or 250 ml (125 doses) are closed with a halogenobutyl rubber stopper (type I, Ph. Eur.) and sealed with an aluminium cap.

Pack sizes:

Cardboard box with 1 vial of 20 ml.
Cardboard box with 10 vials of 20 ml.
Cardboard box with 1 vial of 50 ml.
Cardboard box with 10 vials of 50 ml.

Cardboard box with 1 vial of 100 ml.
Cardboard box with 1 vial of 250 ml.

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

[<> to be adjusted nationally]

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

[to be completed nationally]

7. MARKETING AUTHORISATION NUMBER(S)

[to be completed nationally]

8. DATE OF FIRST AUTHORISATION

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

[to be completed nationally]

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

[to be completed nationally]

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

[DE-AT-BE-BG-CY-CZ-DK-EE-ES-FR-EL-HR-HU-IT-LT-LU-LV-NL-PL-PT-RO-SI-SK-XI]

Veterinary medicinal product subject to prescription.

[IE] Veterinary medicinal product not 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

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Ery+Parvo+Lepto suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Inactivated *Erysipelothrix rhusiopathiae*, Porcine parvovirus and *Leptospira*

3. PACKAGE SIZE

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

4. TARGET SPECIES

Pigs for reproduction.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: zero days.

8. EXPIRY DATE

EXP {mm/yyyy}

Once broached 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}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

PET vials (20 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Ery+Parvo+Lepto



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Inactivated *Erysipelothrix rhusiopathiae*, Porcine parvovirus and *Leptospira*
20 ml (10 doses)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

EXP {mm/yyyy}
Once broached use within 10 hours.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

PET vials (50, 100 and 250 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Ery+Parvo+Lepto suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Inactivated *Erysipelothrix rhusiopathiae*, Porcine parvovirus and *Leptospira*
50 ml (25 doses)
100 ml (50 doses)
250 ml (125 doses)

3. TARGET SPECIES

Pigs for reproduction

4. ROUTES OF ADMINISTRATION

Intramuscular use. Read the package leaflet before use.

5. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days.

6. EXPIRY DATE

EXP {mm/yyyy}
Once broached 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}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

1. Name of the veterinary medicinal product

Porcilis Ery+Parvo+Lepto suspension for injection for pigs

2. Composition

Each 2 ml dose contains:

Active substances:

Inactivated strains of:

<i>Erysipelothrix rhusiopathiae</i> , serotype 2 (strain M2)	≥ 1 ppd ¹
Porcine parvovirus (strain 014)	≥ 130 U ²
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<i>Leptospira interrogans</i> serogroup Icterohaemorrhagiae serovar Copenhageni (strain Ic-02-001)	≥ 210 U ²
<i>Leptospira interrogans</i> serogroup Australis serovar Bratislava (strain As-05-073)	≥ 1310 U ²
<i>Leptospira kirschneri</i> serogroup Grippotyphosa serovar Dadas (strain Gr-01-005)	≥ 648 U ²
<i>Leptospira interrogans</i> serogroup Pomona serovar Pomona (strain Po-01-000)	≥ 166 U ²
<i>Leptospira santarosai</i> serogroup Tarassovi serovar Gatuni (strain S1148/02)	≥ 276 U ²

Adjuvant:

dl- α -tocopheryl acetate 150 mg

¹ Pig protective dose as compared to a reference preparation known to be protective in pigs.

² As determined in the *in vitro* antigenic mass ELISA potency test.

Homogenous white to nearly white suspension after shaking.

3. Target species

Pigs for reproduction.

4. Indications for use

For the active immunisation of pigs:

- to reduce clinical signs (skin lesions and fever) of swine erysipelas caused by *Erysipelothrix rhusiopathiae*, serotype 1 and serotype 2.
- to reduce transplacental infection, viral load and fetal mortality caused by Porcine parvovirus.
- to reduce clinical signs (increase of body temperature and reduction in feed intake or activity), infection and bacterial excretion caused by *L. interrogans* serogroup Canicola serovar Canicola.
- to reduce clinical signs (increase of body temperature and reduction in feed intake or activity), severity of infection and foetal mortality caused by *L. interrogans* serogroup Pomona serovar Pomona.
- to reduce infection caused by *L. interrogans* serogroup Icterohaemorrhagiae serovars Copenhageni and Icterohaemorrhagiae, *L. interrogans* serogroup Australis serovar Bratislava, *L. kirschneri* serogroup Grippotyphosa serovars Grippotyphosa and Bananal/Liangguang, *L. weilii* serogroup Tarassovi serovar Vughia and *L. borgpetersenii* serogroup Tarassovi serovar Tarassovi.

Onset of Immunity:

E. rhusiopathiae: 3 weeks

Porcine parvovirus: 10 weeks

Leptospira serogroups: 2 weeks

Duration of Immunity:

E. rhusiopathiae: 6 months

Porcine parvovirus: 1 year

Leptospira serogroup Australis: 6 months

Leptospira serogroups Canicola, Icterohaemorrhagiae, Grippotyphosa, Pomona and Tarassovi: 1 year

5. Contraindications

None.

6. Special warnings

Special warnings:

Vaccinate healthy animals only.

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

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

Pregnancy and lactation:

Can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interactions:

No information is available on the safety and efficacy of this vaccine 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 adverse events other than those mentioned in section “Adverse events” were observed after the administration of a double dose of vaccine.

Major incompatibilities:

Do not mix with any other veterinary medicinal product.

7. Adverse events

Pigs for reproduction:

Very common (>1 animal / 10 animals treated):	Elevated temperature ¹ Injection site swelling ²
Uncommon (1 to 10 animals / 1,000 animals treated):	Decreased activity ³ , reduced food intake ³
Rare (1 to 10 animals / 10,000 animals treated):	Vomiting ⁴ , reddening of the skin ⁴ , tachypnoea (rapid breathing) ⁴ , twitching ⁴
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction

¹ The observed mean increase was 0.5 °C (in individual cases the maximum increase was 1.5 °C) up until 2 days after vaccination.

² Local reactions, mostly consisting of red, mild to hard, non-painful swellings. In general, local reactions may have a diameter of ≤ 5 cm, and in very rare cases local reactions in individual animals can

be up to 20 cm in diameter. All local reactions disappear completely within approximately 2 weeks after vaccination.

³ Feed intake and activity are completely restored within a week.

⁴ Intermediate systemic reactions, which resolve in a few minutes.

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

For intramuscular use. Administer a single dose of 2 ml in the neck region.

Basic vaccination scheme: Pigs which have not yet been vaccinated shall be given a primary injection 6 to 8 weeks before the expected date of insemination and a booster injection 4 weeks later.

Revaccination: A single revaccination with the veterinary medicinal product should be given once a year. Six months post each vaccination with the veterinary medicinal product, a single revaccination with an *Erysipelothrix rhusiopathiae* containing product should be given to maintain immunity against *Erysipelothrix rhusiopathiae*. In case of known infection pressure with *L. interrogans* serogroup Australis, a single revaccination with the veterinary medicinal product should be given every six months, as it is unknown if or for how long the duration of immunity for this serogroup persists beyond six months.

9. Advice on correct administration

Before use allow the vaccine to reach room temperature.

Shake well before use.

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.

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 how to dispose of medicines no longer required.

[< > to be adjusted nationally]

13. Classification of veterinary medicinal products

[DE-AT-BE-BG-CY-CZ-DK-EE-ES-FR-EL-HR-HU-IT-LT-LU-LV-NL-PL-PT-RO-SI-SK-XI]

Veterinary medicinal product subject to prescription.

[IE] Veterinary medicinal product not subject to prescription

14. Marketing authorisation numbers and pack sizes

{to be completed nationally}

Cardboard box with 1 vial of 20 ml.

Cardboard box with 10 vials of 20 ml.

Cardboard box with 1 vial of 50 ml.

Cardboard box with 10 vials of 50 ml.

Cardboard box with 1 vial of 100 ml.

Cardboard box with 1 vial of 250 ml.

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

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

{{[< > to be adjusted nationally]}}

< Local representative> <and contact details to report suspected adverse reactions>:

{{[< > to be adjusted nationally]}}

17. Other information

[To be completed nationally where applicable]

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