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:	
Erysipelothrix rhusiopathiae, serotype 2 (strain M2)	≥ 1 ppd[1]
Porcine parvovirus (strain 014)	≥ 130 U[2]
Leptospira interrogans serogroup Canicola serovar Portland-Vere (strain Ca-12-000)	≥ 2816 U[2]
Leptospira interrogans serogroup Icterohaemorrhagiae serovar Copenhageni (strain Ic-02-001)	≥ 210 U[2]
Leptospira interrogans serogroup Australis serovar Bratislava (strain As-05-073)	≥ 1310 U[2]
Leptospira kirschneri serogroup Grippotyphosa serovar Dadas (strain Gr-01-005)	≥ 648 U[2]
Leptospira interrogans serogroup Pomona serovar Pomona (strain Po-01-000)	≥ 166 U[2]
Leptospira santarosai 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 the package leaflet for respective contact details.

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 Grippotyphosa serovars Grippotyphosa 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

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

Intervet Ireland Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10996/279/001

8. DATE OF FIRST AUTHORISATION

16 December 2016

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

25 June 2023

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

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).