1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Ery+Parvo+Lepto suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 2 ml 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:

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

Pig for reproduction.

4.2 Indications for use, specifying the target species

For the active immunization 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 foetal 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: 12 months
Leptospira serogroup Australis: 6 months
Leptospira serogroups Canicola, Icterohaemorrhagiae, Grippotyphosa, Pomona and Tarassovi: 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 the label to the physician.

4.6 Adverse reactions (frequency and seriousness)
An increase in body temperature may very commonly occur up until two days after vaccination. The observed mean increase was 0.5°C (in individual cases the maximum increase was 1.5°C). Transient local reactions, mostly consisting of red, mild to hard, non-painful swellings are a very common observation. In general, local reactions may have a diameter of ≤ 5 cm, 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. In individual animals intermediate systemic reactions, such as vomiting, redness, rapid breathing and twitching, may rarely be observed, which resolve in a few minutes. In individual animals transient reductions in feed intake or activity may uncommonly occur. Feed intake and activity are completely restored within a week.

In post marketing experience:
A hypersensitivity reaction may occur in very rare cases.

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
Pregnancy and lactation:
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

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 *Erysipelotrix rhusiopathiae* containing product should be given to maintain immunity against *Erysipelotrix 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.

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

No adverse reactions other than those mentioned in section 4.6 were observed after the administration of a double dose of vaccine.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Suidae. Inactivated viral and inactivated bacterial vaccine for pigs. ATC vet code: QI09AL07.

The 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

dl-α-tocopheryl acetate
Polysorbate 80
Simethicone
Sodium chloride
Potassium Chloride
Potassium dihydrogen phosphate
Disodium phosphate dihydrate
Water for injection

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 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 size:
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.

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

10. DATE OF REVISION OF THE TEXT
05/2021

PROHIBITION OF SALE, SUPPLY AND/OR USE
Not applicable.