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:

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

Pigs for reproduction.

4.2 Indications for use, specifying the 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

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.

Special precautions for the protection of the environment:
Not applicable.

Other precautions:
Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Pig 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 two 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, 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, 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.

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 Amount(s) 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 *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.

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

No adverse events 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; porcine parvovirus + erysipelothrix + leptospira.
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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polysorbate 80
Simethicone
Sodium chloride
Potassium chloride

Potassium dihydrogen phosphate
Disodium phosphate dihydrate
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 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

Medicines should not be disposed of via wastewater.
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.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 06376/5010

9. DATE OF FIRST AUTHORISATION

22 December 2016

10. DATE OF REVISION OF THE TEXT

December 2024

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

Gavin Hall

Approved 10 December 2024