1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Ery+Parvo 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*
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:

Qualitative composition of excipients and other constituents
Polysorbate 80
Tris (hydroxymethyl) aminomethane
Sodium chloride
Simethicone
Hydrochloric acid
Water for injections

Homogenous white to nearly white suspension after shaking.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (sows and gilts).

3.2 Indications for use for each target species

For active immunisation of sows and gilts to prevent clinical signs of Erysipelas disease caused by all relevant *Erysipelothrix rhusiopathiae* serotypes (serotype 1 and 2) and for protection against embryonal and foetal death caused by porcine parvovirus (PPV) infection.

E. rhusiopathiae:
Onset of immunity (after primary vaccination course): 3 weeks.
Duration of immunity: 6 months.

Porcine parvovirus:
Onset of immunity: has not been established.
Duration of immunity: 12 months.

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 label to the physician.

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

3.6 Adverse events

Pigs (sows and gilts):

Very common (>1 animal / 10 animals treated):	Elevated temperature[1]. Injection site swelling[2].
Common (1 to 10 animals / 100 animals treated):	Reluctant to move[3].
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction.

[1] Transient increase (0.5 °C) within 24 hours.
[2] Mild local swelling (Ø 1-10 mm) until 8 days.
[3] Transient reaction.

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 the national competent authority via the national reporting system. See 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

Intramuscular use.
Administer one 2 ml dose 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 administration of this combined Erysipelas and PPV 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 administered once a year, supplemented with the administration of a single Erysipelas vaccine 6 months after each vaccination with this combined Erysipelas and PPV vaccine.

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

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

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: QI09AL01

The active substances are a lysate of *E. rhusiopathiae* strain M2 (serotype 2) and inactivated porcine parvovirus strain 014.

For the active immunisation of sows and gilts, as an aid in the control of swine erysipelas and for the protection of their embryos and foetuses against porcine parvovirus infection.
The antigens are incorporated in an aqueous tocopherol based adjuvant to enhance prolonged stimulation of immunity.

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 (polyethylene terephthalate) vial closed with a halogenobutyl rubber stopper and sealed with a coded aluminium cap.

Package sizes:
Cardboard box with 1 vial of 20 ml (10 doses), 50 ml (25 doses), 100 ml (50 doses) or 250 ml (125 doses).
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)

VPA 10996/097/001

8. DATE OF FIRST AUTHORISATION

04 May 2001

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

09 February 2024

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).