SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Ery suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (2 ml) contains:

Active substance:
Inactivated lysed antigen concentrate of Erysipelothrix rhusiopathiae strain M2 (serotype 2): ≥ 1 pig protective dose (ppd)*
*as measured in the Ph. Eur. Potency test.

Adjuvant:
dl-α-tocopherol acetate: 150 mg

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
Aqueous white or nearly white liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs.

4.2 Indications for use, specifying the target species

For active immunisation of pigs to prevent clinical signs of Erysipelas disease caused by all relevant Erysipelothrix rhusiopathiae serotypes (serotype 1 and 2).

Onset of immunity: 3 weeks
Duration of immunity: 6 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
Sick and weak animals should not be vaccinated.

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)

In laboratory studies and field trials:
Transient increases in body temperature (0.5°C) within 24 hours may very commonly occur. Mild transient local swelling (Ø 1-10mm) until 8 days after vaccination may very commonly occur. Transient reluctance to move may commonly occur.

In post marketing experience:
In very rare cases, a hypersensitivity reaction may occur.

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

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 except Porcilis Parvo vaccine 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

Administer one dose of 2 ml by deep intramuscular injection behind the ear.

Initial vaccination:
A single dose of vaccine in pigs from an age of 10 weeks onwards.
Repeat vaccination 4 weeks later.

Booster vaccination:
Revaccinations should be twice a year.

Before using vaccine allow it to reach room temperature (15 °C – 25 °C)
Shake vial before and regularly during use.
Use sterile syringe and needles. Avoid introduction of contamination by multiple broaching.

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

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

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Erysipelas vaccine.
ATC-vet code: QI09AB03.

The active substance is a lysate of E. rhusiopathiae strain M2 (serotype 2).
For active immunisation of pigs, as an aid in the control of swine erysipelas. The antigen is incorporated in an aqueous tocopherol based adjuvant in order to enhance a prolonged stimulation of immunity.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

dl-α-tocopherol acetate
Polysorbate 80
Simethicone
Sodium chloride
Tris (hydrocymethyl) aminomethane
Hydrochloric acid
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

PETvial closed with a halogenobutyl rubber stopper and sealed with a coded aluminium cap.

Package sizes:
1 vial of 20 ml (10 doses), 50 ml (25 doses), 100 ml (50 doses) or 250 ml (125 doses) packed in a cardboard box.
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.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 06376/4138

9. DATE OF FIRST AUTHORISATION

07 July 1997

10. DATE OF REVISION OF THE TEXT

January 2025

Gavin Hall
Approved: 13 January 2025