# **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:

*Erysipelothrix rhusiopathiae*, serotype 2, strain M2, inactivated: ≥ 1 pig protective dose (ppd)\*

#### Adjuvant:

dl-α-tocopherol acetate: 150 mg

# **Excipients:**

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

Homogenous white to nearly white suspension after shaking.

# 3. CLINICAL INFORMATION

# 3.1 Target species

Pigs.

## 3.2 Indications for use for each target species

For the 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.

<sup>\*</sup>as measured in the Ph. Eur. Potency test.

## 3.3 Contraindications

None.

## 3.4 Special warnings

Vaccinate healthy animals only.

## 3.5 Special precautions for use

<u>Special precautions for safe use in the target species:</u> 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.

<u>Special precautions for the protection of the environment:</u> Not applicable.

#### 3.6 Adverse events

#### Pigs:

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

<sup>&</sup>lt;sup>1</sup> Transient increases in body temperature (0.5 °C) within 24 hours.

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.

<sup>&</sup>lt;sup>2</sup> Mild and transient (diameter 1-10 mm) until 8 days after vaccination.

<sup>&</sup>lt;sup>3</sup> Transient.

### 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 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.

## 3.9 Administration routes and dosage

Intramuscular use.

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 the vaccine allow it to reach room temperature (15  $^{\circ}$ C – 25  $^{\circ}$ C). Shake the vial before and regularly during use.

Use sterile syringe and needles. Avoid introduction of contamination by multiple broaching.

# 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.

Section 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" should be included.

Not applicable.

#### 3.12 Withdrawal periods

Zero days.

#### 4. IMMUNOLOGICAL INFORMATION

#### 4.1 ATCvet 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.

#### 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  $^{\circ}$ C – 8  $^{\circ}$ C). Do not freeze. Protect from light.

## 5.4 Nature and composition of immediate packaging

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

#### Pack sizes:

Cardboard box containing one 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 product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

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 International B.V.

## 7. MARKETING AUTHORISATION NUMBER

Vm 06376/4138

# 8. DATE OF FIRST AUTHORISATION

07 July 1997.

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

July 2025

# 10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on <a href="https://www.gov.uk">www.gov.uk</a>.

Gavin Hall

Approved: 22 September 2025