Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis ERY suspension for injection for pigs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose contains:

Active substance:
Inactivated lysed antigen concentrate of *Erysipelothrix rhusiopathiae* strain M2 (serotype 2): ≥ 1 ppd*

*ppd = pig protective dose, determined by reference to a standard vaccine batch

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 (sows, gilts, boars and growing pigs).

4.2 Indications for use, specifying the target species

For the active immunisation of healthy pigs to reduce clinical signs and lesions caused by erysipelas disease.
To maintain protection, animals should be re-vaccinated at no more than six monthly intervals.

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 the case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. If spilled on the skin, wash with soap and water. If ingested, drink water. If symptoms develop, seek medical advice.

4.6 Adverse reactions (frequency and seriousness)

Transient increases in body temperature (0.5°C) within 24 hours may very commonly occur. A mild transient local swelling (less than 5cm in diameter, normally within 3 days) 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.
Stress should be avoided when vaccinating animals, particularly during later stages of pregnancy.

4.8 Interaction with other medicinal products and other forms of interactions

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 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 per pig by deep intramuscular injection behind the ear.
Ensure that vaccination equipment is clean and sterile before use. Avoid the introduction of contamination by multiple broaching.
Allow vaccine to reach room temperature (15° - 25°C) before use.
Shake well before and during use.

Vaccination programmes

Young growing pigs:
Pigs should be at least 6 weeks of age. A course of two doses given 4 weeks apart, is recommended.

Breeding stock:
Primary vaccination: For the induction of protection against erysipelas, an initial course of two doses, given 4 weeks apart, is recommended. Where protection against parvovirus is also required, this can be achieved with Porcilis Ery given either 4 weeks before, or 4 weeks after, administration of the Porcilis Ery+Parvo. Boars, sows and gilts should be vaccinated against *E. rhusiopathiae* at least 2 weeks before mating.
Booster vaccination: Sows and boars should be vaccinated (a single dose of 2 ml) against erysipelas at six monthly intervals. For sows this may be during each lactation period, at weaning or during pregnancy (avoiding the last two weeks).

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

No additional symptoms, other than those observed following a single dose, were observed following administration of a double dose.

4.11 Withdrawal period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Erysipelas vaccine.
ATC-vet code: QI09AB
The active ingredient is an inactivated antigen of *Erysipelothrix rhusiopathiae* which induces active immunity in vaccinated animals. 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 (declared in product literature)
Sodium chloride
Tris(hydroxymethyl)aminomethane
Polysorbate 80
Simethicone
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: 24 months.

Shelf life after first opening the immediate packaging : 10 hours.

6.4 Special precautions for storage

Store in a refrigerator (2°C to 8°C). Do not freeze. Protect from light.
Care should be taken to avoid prolonged or repetitive exposure to high ambient temperatures following withdrawal from the refrigerator prior to use.

6.5 Nature and composition of immediate packaging

PET-vial 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 presentations may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited
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Magna Business Park, Citywest Road
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10996/096/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10 April 2001
Date of last renewal: 07 July 2006

10 DATE OF REVISION OF THE TEXT

December 2020