# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Ery + Parvo

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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|---|---|
| *Erysipelothrix rhusiopathiae* strain M2 (Serotype 2) | > 1 ppd* |
| Porcine Parvo virus strain 014 | ≥ 7.4 $\log_2$ HI** units |

*ppd dose = pig protective dose, determined by reference to a standard vaccine batch
**HI units = Haemagglutination inhibition antibody titre determined in guinea pigs

Excipients:

Adjuvant:

| | |
|---|---|
| dl-α–Tocopherol acetate | 150.00 mg |

Preservative:

| | |
|---|---|
| Formaldehyde | 0.05% |

## 3 PHARMACEUTICAL FORM

Suspension for injection.

## 4 CLINICAL PARTICULARS

### 4.1 Target Species

Pigs (sows and gilts)

### 4.2 Indications for use, specifying the target species

For the active immunisation of sows and gilts to reduce clinical signs and lesions caused by erysipelas disease and to prevent or reduce mortality and clinical signs of parvovirus infection on embryos and foetuses during pregnancy.

### 4.3 Contraindications

None.

## 4.4 Special warnings for each target species

Only healthy animals should be vaccinated.
After vaccination with Porcilis Ery + Parvo, animals may seroconvert and detectable levels of antibody to PPV may persist.
PPV infection is not the only cause of reproductive failure in pigs.

A good immune response is reliant on the reaction of an immunogenic agent and a fully competent immune system. Immunogenicity of the vaccine antigen will be reduced by poor storage or inappropriate administration. Immunocompetence of the animal may be compromised by a variety of factors including poor health, nutritional status, genetic factors, concurrent drug therapy and stress.

It is advisable to vaccinate all animals in a herd in order to minimise the infectious potential unless there is a contraindication. Failure to vaccinate individual animals may promote the transmission of pathogens and development of disease.

## 4.5 Special precautions for use

**Special precautions for use in animals**

None

**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 insert 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)

Vaccination reactions normally consist of a slight swelling (0.5° C), transient (normal within 24 hours) rise in body temperature. A mild local swelling (less than 5 cm in diameter, normal within 3 days) and some reluctance to move may be seen in a very small proportion (< 5%) of vaccinated animals.

## 4.7 Use during pregnancy, lactation or lay

Porcilis Ery + Parvo is safe to use during pregnancy and lactation.
Stress should be avoided when vaccinating animals, particularly during the later stages of pregnancy.

## 4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy from the concurrent use of this product with any other. It is therefore recommended that no other vaccines should be administered within 14 days before or after vaccination with Porcilis Ery + Parvo.

## 4.9 Amounts to be administered and administration route

The dose is 2 ml per pig, given by deep intramuscular injection behind the ear. Pigs should be at least 6 months of age.

Vaccination Programme:
**Primary Vaccination:** Gilts should be vaccinated against *E. rhusiopathiae* and Porcine Parvo virus (PPV) before first mating. A single dose, not less than 2 weeks before mating, is sufficient to protect the following pregnancy from damage due to PPV. For the induction of protection against Erysipelas, an initial course of two doses is recommended. This can be achieved with the single component Porcilis Ery given either 4 weeks before or 4 weeks after the administration of Porcilis Ery + Parvo.

Booster vaccination: Sows should be revaccinated against erysipelas during each lactation period (i.e. at no more than 6 month intervals) and against PPV annually (e.g. by alternate vaccinations with Porcilis Ery and Porcils Ery + Parvo).

Allow vaccine to reach ambient temperature (15-25°C) before use.
Shake vigorously before and at intervals during use.
Clean and sterile equipment should be used and care should be taken to administer the vaccine in an aseptic fashion.

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

The vaccine has been shown to be safe at twice the recommended dose. Accidental overdosage is unlikely to cause any reaction other than those described in Section 4.6.

## 4.11 Withdrawal Period(s)

Zero Days.

## 5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

QI09AL01
The active ingredients are inactivated antigens of *Erysipelothrix rhusiopathiae* and Porcine Parvo virus which induce active immunity in vaccinated animals. The antigens are incorporated in an aqueous tocopherol based adjuvant in order to give a prolonged stimulation of immunity.

## 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

dl-α–Tocopherol acetate - declared on product literature
Formaldehyde Solution (35%) - declared on product literature
Polysorbate 80
Simethicone
Sodium chloride
Tris(hydroxymethyl)aminomethane
Water for injections

## 6.2 Incompatibilities

Not to be mixed with any other product.

## 6.3 Shelf-life

Shelf-life is 24 months.
In-use shelf life: 10 hours.

## 6.4 Special precautions for storage

Store at between +2 and +8°C. Protect from light. Do not freeze.
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

Type I (Ph.Eur) glass or PET bottles closed with a halogenated rubber stopper and sealed with a colour coded aluminium cap containing 10, 25, 50 or 125 doses (20, 50, 100 or 250 ml respectively).
Not all pack sizes may be marketed.

## 6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused product or waste material should be disposed of in accordance with national requirements.

# 7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd.,
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

# 8 MARKETING AUTHORISATION NUMBER(S)

VPA No. 10996/097/001

# 9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

7th July 2006

# 10 DATE OF REVISION OF THE TEXT

22nd May 2008