Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Parvo

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 dose (2 ml) contains:

Active substance
Inacivated porcine parvovirus (PPV) strain 014 ≥ 552 EU*

Adjuvant:
dl-α-tocopherol acetate 150 mg

Excipients:
Formaldehyde 1.08 mg

For a full list of excipients, see section 6.1.

*as determined in the final product antigenic mass ELISA

3 PHARMACEUTICAL FORM

Suspension for injection.
Nearly white liquid.

4 CLINICAL PARTICULARS

4.1 Target Species

Sows and gilts

4.2 Indications for use, specifying the target species

For the active immunisation of sows and gilts to prevent or reduce mortality and clinical signs of porcine parvovirus infection on embryos and foetuses during pregnancy.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Only healthy animal***s*** should be vaccinated.
After vaccination with Porcilis 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.

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 (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

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

4.8 Interaction with other medicinal products and other forms of interactions

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

Primaryvaccination
The minimum age for vaccination is 6 months.
Gilts and sows should be vaccinated once 2-3 weeks before service.

Booster vaccination
Revaccination of sows is recommended at intervals of not more than one year, sows being vaccination at least 2 weeks before mating/artificial insemination.

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

QI09AA02
The active ingredient, an inactivated Porcine Parvovirus antigen, induces active immunity in vaccinated animals. The antigen is incorporated in an aqueous tocopherol based adjuvant, to provide a prolonged stimulation of immunity.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Formaldehyde (declared in product literature)
Polysorbate 80
Simethicone
Sodium chloride
Water for injections

6.2 Major incompatibilities

Do not mix with any other vaccine or immunological product.

6.3 Shelf-life

2 years

After first opening: 10 hours at 15-25°C.

6.4 Special precautions for storage

Store at 2-8°C. Do not freeze.

6.5 Nature and composition of immediate packaging

20, 50 or 100 ml PET-bottles (polyethylene terephthalate: PET) or vials of type I (Ph.Eur.) glass are filled with respectively 10, 25 or 50 doses and are closed with a nitryl rubber stopper (Ph.Eur.) and sealed with a coded aluminium cap.
Box with 1 bottle of 10 (20ml), 25 (50ml) or 50 doses (100ml) and box with 10 bottles of 10 doses (20 ml)

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

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

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited
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Magna Business Park, Citywest Road
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8 MARKETING AUTHORISATION NUMBER(S)

VPA10996/098/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th April 2001
Date of last renewal: 7th July 2006

10 DATE OF REVISION OF THE TEXT

October 2015