Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis PRRS lyophilisate and solvent for suspension for injection for pigs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 2 ml (intramuscular application) or 0.2 ml (intradermal application) of reconstituted vaccine contains:

Lyophilisate:
Active substance:
Live attenuated PRRS virus strain DV: $10^{4.0}$ - $10^{6.3}$ $TCID_{50}$*

Solvent:
Adjuvant:
dl-α-tocopheryl acetate: 75 mg/ml

For the full list of excipients, see section 6.1.

*tissue culture infective dose 50 %

3 PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

Lyophilisate: light yellow to white cake.
Solvent: white solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs.

4.2 Indications for use, specifying the target species

For active immunisation of clinically healthy pigs in a PRRS virus contaminated environment, to reduce viraemia caused by infection with European strains of PRRS virus.

Specific claims
For finishing pigs, the effect of the virus on the respiratory system is most relevant. A significant improvement of rearing results (reduced morbidity due to PRRS infection, and a better daily growth and feed conversion) until the end of the fattening period was observed in vaccinated pigs during field trials, particularly in piglets vaccinated at 6 weeks of age.
For breeding pigs, the effect of the virus on the reproductive system is most relevant. A significant improvement of the reproductive performance in PRRS virus contaminated environments and a reduction of transplacental virus transmission after challenge was observed in vaccinated pigs.

Onset of Immunity: 28 days post vaccination.
Duration of immunity: at least 24 weeks.

4.3 Contraindications

Do not use in herds where the prevalence of European PRRS virus has not been established through reliable diagnostic methods.

4.4 Special warnings for each target species

Porcilis PRRS must only be used in PRRS virus contaminated herds, where prevalence of European PRRS virus has been established through reliable diagnostic virological methods. No data are available on the safety of the vaccine for the reproductive performance in boars. Do not use in herds where a PRRS eradication programme based on serology has been adopted.

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals
Care should be taken to avoid the introduction of the vaccine strain into an area where PRRS virus is not already present. The vaccine virus may spread to pigs in contact during 5 weeks after vaccination. The most common spreading route is via direct contact, but spreading via contaminated objects or via the air cannot be excluded. Care should be taken to avoid spread of vaccine virus from vaccinated animals to unvaccinated animals (e.g.: naïve pregnant sows) that should remain free from PRRS virus. Do not use in boars producing semen for seronegative herds, as PRRS virus may be excreted in semen for many weeks.

Do not routinely rotate two or more commercial PRRS MLV vaccines based on different strains in a herd.

In order to limit the potential risk of recombination between PRRS MLV vaccine strains of the same genotype, do not use different PRRS MLV vaccines based on different strains of the same genotype on the same farm at the same time. In the case of transitioning from one PRRS MLV vaccine to another PRRS MLV vaccine, a transition period should be respected between the last administration of the current vaccine and the first administration of the new vaccine. This transition period should be longer than the shedding period of 5 weeks following vaccination.

PRRS virus-naïve breeding animals (e.g. replacement gilts from PRRS virus-negative herds) which are introduced into a PRRSV-infected herd should be vaccinated prior to first insemination. Vaccination should preferably be done in a separated quarantine unit. A transition period should be respected between vaccination and moving the animals to the breeding unit. This transition period should be longer than the shedding phase of 5 weeks following vaccination.

Vaccination should aim to achieve a homogenous immunity in the target population at farm level.

Special precautions to be taken by the person administering the vetrinary 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:
Systemic or local reactions may be observed after vaccination.

After intramuscular vaccination a transient hyperthermia may rarely occur. Vaccination can evoke hypersensitivity reactions such as dyspnoea, hyperaemia, and decubitus in rare cases. These signs disappear spontaneously and totally within a few minutes after vaccination.

After intradermal application a small firm intradermal lump (maximum 1.5 cm in diameter) is observed and is indicative of the appropriate vaccination technique. This dermal lump is generally seen for less than 14 days but may occasionally persist for 29 days or longer.

In post marketing experience:
Vaccination can evoke hypersensitivity reactions such as tremor, excitation and vomiting in rare cases. These signs normally disappear spontaneously and totally within a few minutes after vaccination. However, fatal anaphylactic reactions have occurred in very rare cases.

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

Pregnancy:
PRRS virus-naïve gilts and sows should not be vaccinated during pregnancy, as this can have negative effects. Vaccination during pregnancy is safe when it is performed in gilts and sows which are already immunized against European PRRS virus via vaccination or field infection.

Lactation:
The vaccine can be used during lactation.

4.8 Interaction with other medicinal products and other forms of interactions

Safety and efficacy data for intramuscular injection are available in finishing pigs from 4 weeks of age onwards, which demonstrate that this vaccine can be mixed with Porcilis M Hyo.
The product literature of Porcilis M Hyo should be consulted before administration of the mixed product. No information is available on the safety and efficacy of the use of Porcilis PRRS mixed with Porcilis M Hyo, in breeding animals or during pregnancy.

Furthermore, safety and efficacy data are available for both routes of administration in finishing pigs from 3 weeks of age onwards, which demonstrate that this vaccine can be given with Porcilis PCV M Hyo, with Porcilis Lawsonia, or with a mixture of Porcilis PCV M Hyo and Porcilis Lawsonia, at the same time, but at separate sites (preferably at the opposite side of the neck).
The product literature of Porcilis PCV M Hyo and/or Porcilis Lawsonia should be consulted before administration.
In individual pigs the temperature increase after associated use may commonly exceed 2°C. The temperature returns to normal from 1 to 2 days after the peak temperature is observed. Transient local injection site reactions, which are restricted to a slight swelling (maximum 2 cm diameter), may commonly occur from 5 days after vaccination onwards, after intradermal and after intramuscular vaccination. These reactions may occasionally persist until 29 days after vaccination or longer. Hypersensitivity reactions after vaccination may occur uncommonly.
No information is available on the safety and efficacy of the administration of Porcilis PRRS in association with Porcilis PCV M Hyo and/or Porcilis Lawsonia at the same time at separate sites in breeding animals or during pregnancy.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product, except the products mentioned above. 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

Reconstitute the vaccine with the corresponding adjuvanting diluent (use only Diluvac Forte).

Number of doses per vial	Volume (ml) of diluent needed for	
	intramuscular injection	intradermal application
10	20	2
25	50	5
50	100	10
100	200	20

Before using the vaccine allow it to reach room temperature (15 °C – 25 °C) and shake well before use.

Dosage:
Intramuscular injection: 2 ml in the neck.
Intradermal application: 0.2 ml on top or to the left or right side of the neck, or along the muscles of the back, using an intradermal device.
A small, transient, intradermal lump observed after the intradermal application is indicative of the appropriate vaccination technique.

Vaccination scheme:
A single dose is given to pigs from 2 weeks of age onwards.

Finishing pigs: a single vaccination is sufficient for protection until slaughter.
Breeding pigs: For gilts a (re)vaccination 2-4 weeks before mating is recommended.
To maintain a high and homologous level of immunity, revaccination at regular intervals is recommended, either before each next gestation or at random at 4 month intervals. Pregnant sows should only be vaccinated after previous exposure to European PRRS virus.

Maternally derived antibodies may interfere with the response to vaccination.

The vaccine may be reconstituted shortly before vaccination for simultaneous use with Porcilis M Hyo in finishing pigs from 4 weeks of age and the following instructions should be used:

Porcilis PRRS	Porcilis M Hyo
10 doses	+ 20 ml
25 doses	+ 50 ml
50 doses	+ 100 ml
100 doses	+ 200 ml

A single dose (2 ml) of Porcilis PRRS mixed with Porcilis M Hyo is given intramuscularly in the neck.

Use sterile syringes and needles or clean intradermal equipment.

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

The effects seen after a ten-fold overdose of vaccine virus and a two-fold overdose of solvent were similar to those seen after a single dose of vaccine.

4.11 Withdrawal period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Pig, live PRRS viral vaccine,
ATCvet code: QI09AD03

Intramuscular or intradermal administration of Porcilis PRRS results in the production of specific antibodies and active immunisation against infection caused by European strains of Porcine Reproductive and Respiratory Syndrome virus. Immunity is enhanced by the adjuvant α-tocopherol included in the solvent for reconstitution.
On the basis of antibodies induced by vaccination, it is not possible to discriminate vaccinated animals from those naturally infected with European strains of PRRS virus.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:
culture medium,
chemically defined stabiliser CD#279 (patented)

Solvent:
dl-α-tocopheryl acetate
polysorbate 80
sodium chloride
potassium dihydrogen phosphate
disodium phosphate dihydrate
simethicone

water for injection

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product, except the solvent supplied with the product or with Porcilis M Hyo.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale:
Lyophilisate: 2 years.
Solvent: In glass vials 4 years, in PET vials 2 years.

Shelf life after reconstitution according to directions: 3 hours.
After mixing with Porcilis M Hyo: 1 hour.

6.4 Special precautions for storage

Vaccine or combined packaging: store in a refrigerator (2°C - 8°C). Protect from light.
Solvent: store below 25°C.

6.5 Nature and composition of immediate packaging

Lyophilisate container:
Glass Type I vial (Ph.Eur.), closed with a halogenobutyl rubber stopper (Ph.Eur.) and sealed with a coded aluminium cap.

Solvent container:
Glass Type I vial (Ph.Eur.) or PET-flask, closed with a halogenobutyl rubber stopper (Ph.Eur.) and sealed with a coded aluminium cap.

IM presentation:
Cardboard box with 1 vial of lyophilisate (10 doses)
Cardboard box with 1 vial of lyophilisate (25 doses)
Cardboard box with 1 vial of lyophilisate (50 doses)
Cardboard box with 1 vial of lyophilisate (100 doses)
Cardboard box with 10 vials of lyophilisate (10 doses)
Cardboard box with 10 vials of lyophilisate (25 doses)
Cardboard box with 10 vials of lyophilisate (50 doses)
Cardboard box with 10 vials of lyophilisate (100 doses)
Cardboard box with 1 vial of lyophilisate (10 doses) and 1 vial of solvent (20 ml).
Cardboard box with 1 vial of lyophilisate (25 doses) and 1 vial of solvent (50 ml).
Cardboard box with 1 vial of lyophilisate (50 doses) and 1 vial of solvent (100 ml).
Cardboard box with 1 vial of lyophilisate (100 doses) and 1 vial of solvent (200 ml).
Cardboard box with 10 vials of lyophilisate (10 doses) and 10 vials of solvent (20 ml).
Cardboard box with 10 vials of lyophilisate (25 doses) and 10 vials of solvent (50 ml).
Cardboard box with 10 vials of lyophilisate (50 doses) and 10 vials of solvent (100 ml).
Cardboard box with 10 vials of lyophilisate (100 doses) and 10 vials of solvent (200 ml).
Cardboard box with 1 vial of lyophilisate (10 doses) and a cardboard box with 1 vial of solvent (20 ml).
Cardboard box with 1 vial of lyophilisate (25 doses) and a cardboard box with 1 vial of solvent (50 ml).
Cardboard box with 1 vial of lyophilisate (50 doses) and a cardboard box with 1 vial of solvent (100 ml).
Cardboard box with 1 vial of lyophilisate (100 doses) and a cardboard box with 1 vial of solvent (200 ml).
Cardboard box with 10 vials of lyophilisate (10 doses) and a cardboard box with 10 vials of solvent (20 ml).
Cardboard box with 10 vials of lyophilisate (25 doses) and a cardboard box with 10 vials of solvent (50 ml).
Cardboard box with 10 vials of lyophilisate (50 doses) and a cardboard box with 10 vials of solvent (100 ml).
Cardboard box with 10 vials of lyophilisate (100 doses) and a cardboard box with 10 vials of solvent (200 ml).

ID presentation:
Cardboard box with 1 vial of lyophilisate (10 doses) and 1 vial of solvent (2 ml).
Cardboard box with 1 vial of lyophilisate (25 doses) and 1 vial of solvent (5 ml).

Cardboard box with 1 vial of lyophilisate (50 doses) and 1 vial of solvent (10 ml).
Cardboard box with 1 vial of lyophilisate (100 doses) and 1 vial of solvent (20 ml).
Cardboard box with 5 vials of lyophilisate (10 doses) and 5 vials of solvent (2 ml).
Cardboard box with 5 vials of lyophilisate (25 doses) and 5 vials of solvent (5 ml).
Cardboard box with 5 vials of lyophilisate (50 doses) and 5 vials of solvent (10 ml).
Cardboard box with 5 vials of lyophilisate (100 doses) and 5 vials of solvent (20 ml).

Not all pack sizes 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 materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA10996/128/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 06 June 2003
Date of last renewal: 05 June 2008

10 DATE OF REVISION OF THE TEXT

January 2022