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 injection) or 0.2 ml (intradermal application) of reconstituted vaccine contains:

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

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

For the full list of excipients, see section 6.1.

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: 24 weeks post vaccination.

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

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.

Maternally derived antibodies may interfere with the response to vaccination.

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 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.

Special precautions for the protection of the environment:
Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Pigs:

Very common (>1 animal / 10 animals treated):	Injection site lump.[1]
Rare (1 to 10 animals / 10,000 animals treated):	Hyperthermia[2], hypersensitivity reactions (including dyspnoea, hyperaemia, decubitus, muscle tremor, excitation, vomiting).[3]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactic-type reactions.[4]

[1] After intradermal vaccination a small firm injection site lump (maximum 1.5 cm in diameter) is observed and is indicative of the appropriate vaccination technique. This lump is generally seen for less than 14 days but may occasionally persist for 29 days or longer.
[2] After intramuscular vaccination.
[3] These signs disappear spontaneously and totally within a few minutes after vaccination.
[4] Fatal outcome of anaphylactic-type reactions has been reported very rarely.

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 also the last section of the package leaflet for respective contact details.

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 immunised against European PRRS virus via vaccination or field infection.

Lactation:
Can be used during lactation.

4.8 Interaction with other medicinal products and other forms of interaction

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.

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).
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 injection site lump (maximum 2 cm diameter), may commonly occur from 5 days after vaccination onwards, after intradermal and after intramuscular vaccination. These lumps may occasionally persist until 29 days after vaccination or longer. Hypersensitivity reactions after vaccination may occur uncommonly.

Safety and efficacy data are available in pigs from 3 weeks of age onwards which demonstrate that this vaccine can be administered intradermally non-mixed with Porcilis PCV ID alone or with Porcilis PCV ID mixed with Porcilis Lawsonia ID and/or non-mixed with Porcilis M Hyo ID ONCE providing that administration site of non-mixed vaccines is separated by at least 3 cm. Adverse events are as described in section 4.6, except for injection site lumps of up to 2.5 cm can be observed in individual pigs. These lumps may last 5 weeks and are very commonly accompanied by redness and crusts. Hyperthermia on the day of vaccination (mean 0.3 °C, individual pigs up to 1.2 °C) is common. Lying down and malaise can be uncommonly observed in vaccinated pigs. The product literature of respective products should be consulted before administration in association with Porcilis PRRS. No information is available on the safety and efficacy of the administration of Porcilis PRRS in association with the above-mentioned products 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 Amount(s) to be administered and administration route

Reconstitute the vaccine with the corresponding adjuvating solvent.

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

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

Visual appearance after reconstitution: white suspension.

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 a multi-dose needle-free injection device for intradermal application of liquids suitable to deliver a “jet-stream” volume of vaccine (0.2 ml ± 10 %) through the epidermal layers of the skin.
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.

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. 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-tocopheryl 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:
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.
Do not use with any other veterinary medicinal product except those mentioned in section 4.8.

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.
Shelf life 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 vial, 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 with 5 vials of solvent (20 ml).

Not all pack sizes may be marketed.

6.6 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.
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 International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 06376/5026

9. DATE OF FIRST AUTHORISATION

21 September 2000

10. DATE OF REVISION OF THE TEXT

December 2024

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Gavin Hall

Approved: 23 December 2024