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

Lyophilisate:
**Active substance:**
PRRSV-1, strain DV, Live $10^{4.0}$ – $10^{6.3}$ $TCID_{50}$*
*tissue culture infective dose 50%

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

**Excipients:**

| **Qualitative composition of excipients and other constituents** |
|---|
| *Lyophilisate:* |
| Culture medium |
| Chemically defined stabiliser CD#279 (patented) |
| *Solvent:* |
| Polysorbate 80 |
| Sodium chloride |
| Potassium dihydrogen phosphate |
| Disodium phosphate dihydrate |
| Simethicone |
| Water for injections |

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

## 3. CLINICAL INFORMATION

### 3.1 Target species

Pigs.

## 3.2 Indications for use for each 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.

## 3.3 Contraindications

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

## 3.4 Special warnings

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.

## 3.5 Special precautions for use

Special precautions for safe use in the target species:
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.

### 3.6 Adverse events

Pigs:

| | |
|---|---|
| Very common<br>(>1 animal / 10 animals treated): | Injection site lump.[1] |
| Rare<br>(1 to 10 animals / 10 000 animals treated): | Hyperthermia[2], hypersensitivity reactions (including dyspnoea, hyperaemia, decubitus, muscle tremor, excitation, vomiting).[3] |
| Very rare<br>(<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 in fattening pigs and is indicative of the appropriate vaccination technique. In breeding pigs, a mean diameter of approximately 2 cm is observed and in individual breeding pigs up to 10 cm. These lumps may be accompanied by other signs of inflammation (pain, reddening, warmth and crusts). 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 the package leaflet for respective contact details.

### 3.7 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.

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

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 3.6, 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.

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 M Hyo ID alone or with Porcilis PCV M Hyo ID mixed with Porcilis Lawsonia ID. The administration site of non-mixed vaccines should be separated by approximately 3 cm. The product literature of Porcilis PCV M Hyo ID and/or Porcilis Lawsonia ID should be consulted before administration. Adverse events are as described in section 3.6, except for injection site swellings with a maximum size of up to 15 cm in individual breeding pigs. Injection site swellings may show other signs of inflammation (pain, reddening, warmth and crusts). Elevated temperatures (mean 1.1 °C, individual breeding pigs up to 2.4 °C)

may commonly occur on the day of vaccination. The product literature of Porcilis PCV M Hyo ID and/or Porcilis Lawsonia ID should be consulted before administration.

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.

### 3.9 Administration routes and dosage

Intramuscular injection or intradermal application.

Reconstitute the vaccine with the corresponding adjuvanting 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.

Use sterile syringes and needles or clean intradermal equipment.

### 3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

### 3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

### 3.12 Withdrawal periods

Zero days.

## 4. IMMUNOLOGICAL INFORMATION

### 4.1 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.

## 5. PHARMACEUTICAL PARTICULARS

### 5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except the solvent supplied with the product .
Do not use with any other veterinary medicinal product except those mentioned in section 3.8.

### 5.2 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.

### 5.3 Special precautions for storage

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

## 5.4 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.

### 5.5 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 or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

## 6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

## 7. MARKETING AUTHORISATION NUMBER

Vm 06376/5026

## 8. DATE OF FIRST AUTHORISATION

21 September 2000

## 9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

October 2026

## 10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

*Gavin Hall*

Approved: 28 October 2026