# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Lawsonia lyophilisate and solvent for emulsion for injection for pigs

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 2 ml reconstituted vaccine contains:

**Active substance (lyophilisate):**
Inactivated *Lawsonia intracellularis* strain SPAH-08 ≥ 5323 U[1]

[1] Antigenic mass units as determined in the *in vitro* potency test (ELISA).

**Adjuvant (solvent):**

| | |
|---|---|
| Light mineral oil | 222.4 mg |
| Aluminium(as hydroxide) | 2.0 mg |

**Excipients:**
For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Lyophilisate and solvent for emulsion for injection.

Lyophilisate: white/nearly white pellet/powder.
Solvent: homogenous white to nearly white emulsion after shaking.

## 4 CLINICAL PARTICULARS

### 4.1 Target Species

Pigs.

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

For the active immunisation of pigs from 3 weeks of age to reduce diarrhoea, loss of daily weight gain, intestinal lesions, bacterial shedding and mortality caused by *Lawsonia intracellularis* infection.

Onset of immunity: 4 weeks after vaccination.
Duration of immunity: 21 weeks after vaccination.

### 4.3 Contraindications

None.

### 4.4 Special warnings for each target species

Vaccinate healthy animals only.

### 4.5 Special precautions for use

Special precautions for use in animals
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

To the user:

This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician**:**

This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

**4.6 Adverse reactions (frequency and seriousness)**

An increase in body temperature very commonly occurs (mean 0.6°C, in individual pigs up to 1.3°C). The animals return to normal temperature within 1 day after vaccination. Local injection site reactions in the form of swelling (< 5 cm diameter) may commonly occur and disappear within 23 days.

In post marketing experience:

Anorexia and lethargy have been reported uncommonly.

Anaphylactic-type reactions have been reported very rarely. If such reactions occur, appropriate treatment is recommended.

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**

The safety of the veterinary medicinal product has not been established during pregnancy or lactation.

**4.8 Interaction with other medicinal products and other forms of interactions**

Safety and efficacy data in pigs from 3 weeks of age onwards are available, which demonstrate that this vaccine can be given at the same time with Porcilis PCV M Hyo and/or Porcilis PRRS. When Porcilis Lawsonia is given at the same time with Porcilis PCV M Hyo, these products should be mixed (see section 4.9 below), whereas Porcilis PRRS should always be given at a separate site (preferably at the opposite side of the neck). The product literature of Porcilis PCV M Hyo and/or Porcilis PRRS 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 directly after vaccination, but reactions may not appear until 12 days after vaccination. All these reactions disappear within 6 days. Hypersensitivity reactions after vaccination may occur uncommonly.

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**

Intramuscular use.

Reconstitute the lyophilisate in the solvent or in Porcilis PCV M Hyo as follows:

| Lyophilisate | Solvent or Porcilis PCV M Hyo |
|---|---|
| 50 doses | 100 ml |
| 100 doses | 200 ml |

For proper reconstitution and correct administration, use the following procedure:

1. Allow the solvent or Porcilis PCV M Hyo to reach room temperature and shake well before use.
2. Add 5-10 ml of the solvent or Porcilis PCV M Hyo to the lyophilisate and mix briefly.
3. Withdraw the reconstituted concentrate from the vial and transfer it back into the vial with the solvent or the Porcilis PCV M Hyo. Shake briefly to mix.
4. Use the vaccine suspension within 6 hours of reconstitution. Any vaccine remaining at the end of this time should be discarded.

Needle length and diameter should be adapted to the age of the animal.
Avoid introduction of a contamination by multiple broaching.

Dosage:
A single dose of 2 ml of reconstituted vaccine in pigs starting at 3 weeks of age.
Vaccinate pigs by the intramuscular route in the neck.
Visual appearance after reconstitution: homogenous white to nearly white emulsion after shaking.

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

No adverse reactions other than the local reactions described in section 4.6 and the temperature increases described in section 4.8 were observed after the administration of a double dose of Porcilis Lawsonia reconstituted in Porcilis PCV M Hyo.

**4.11 Withdrawal period(s)**

Zero days.

**5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Inactivated bacterial vaccines (including mycoplasma, toxoid and chlamydia) Lawsonia.
ATC-vet code: QI09AB18.

The product stimulates the development of active immunity against *Lawsonia intracellularis* in pigs.

**6 PHARMACEUTICAL PARTICULARS**

**6.1 List of excipients**

Lyophilisate:
Sodium chloride
Potassium Chloride
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
Water for injections

Solvent:
Light mineral oil
Aluminium hydroxide
Sorbitan oleate
Polysorbate 80
Ethyl alcohol

Glycerol
Sodium chloride
Sodium hydroxide
Water for injections

**6.2 Major incompatibilities**

Do not mix the lyophilisate with any other veterinary medicinal product, except the recommended "Solvent for Porcilis Lawsonia" or Porcilis PCV M Hyo.

**6.3 Shelf-life**

Shelf life of the lyophilisate as packaged for sale: 3 years.
Shelf life of the solvent as packaged for sale: 3 years.
Shelf-life after reconstitution according to directions: 6 hours.

**6.4 Special precautions for storage**

Lyophilisate and solvent:
Store in a refrigerator (2°C – 8°C).
Do not freeze.
Protect from light.

**6.5 Nature and composition of immediate packaging**

Lyophilisate:
Hydrolytic glass Type I vial of 50 doses or 100 doses closed with halogenobutyl rubber stoppers and sealed with aluminium caps.

Solvent:
PET (polyethylene terephthalate) vials of 100 ml (50 doses) or 200 ml (100 doses), closed with nitryl rubber stoppers and sealed with aluminium caps.

Presentations:
Cardboard box with 1 x 50 doses of vaccine and cardboard box with 1 x 100 ml solvent
Cardboard box with 10 x 50 doses of vaccine and cardboard box with 10 x 100 ml solvent

Cardboard box with 1 x 100 doses of vaccine and cardboard box with 1 x 200 ml solvent
Cardboard box with 10 x 100 doses of vaccine and cardboard box with 10 x 200 ml solvent

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)

VPA10996/278/001

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

Date of first authorisation: 08 November 2019

## 10 DATE OF REVISION OF THE TEXT

January 2022