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:
Inactivated *Lawsonia intracellularis* strain SPAH-08 ≥ 5323 U[1]

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

Adjuvants:
Light mineral oil 222.4 mg
Aluminium (as hydroxide) 2.0 mg

Excipients:

Qualitative composition of excipients and other constituents
Lyophilisate:
Sodium chloride
Potassium chloride
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
Water for injections
Solvent:
Sorbitan oleate
Polysorbate 80
Ethyl alcohol
Glycerol
Sodium chloride
Sodium hydroxide
Water for injections

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

3. CLINICAL INFORMATION

3.1 Target species

Pigs.

3.2 Indications for use for each 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.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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 veterinary medicinal 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.

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

3.6 Adverse events

Pigs:

Very common (>1 animal / 10 animals treated):	Elevated temperature[1]
Common (1 to 10 animals / 100 animals treated):	Injection site swelling[2]
Uncommon (1 to 10 animals / 1 000 animals treated):	Anorexia, Lethargy
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Anaphylactic-type reaction[3]

[1] Mean of 0.6 °C, in individual pigs up to 1.3 °C. The animals return to normal temperature within 1 day after vaccination.
[2] < 5 cm diameter, disappear within 23 days.
[3] If such reactions occur, appropriate treatment is recommended.

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

3.8 Interaction with other medicinal products and other forms of interaction

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 3.9 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.

3.9 Administration routes and dosage

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.

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

No adverse reactions other than the local reactions described in section 3.6 and the temperature increases described in section 3.8 were observed after the administration of a double dose of Porcilis Lawsonia reconstituted in Porcilis PCV M Hyo.

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: QI09AB18.

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

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except the recommended "Solvent for Porcilis Lawsonia" or except those mentioned in section 3.8.

5.2 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.

5.3 Special precautions for storage

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

5.4 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.

Pack sizes:
Cardboard box with 1 x 50 doses of lyophilisate and cardboard box with 1 x 100 ml solvent
Cardboard box with 10 x 50 doses of lyophilisate and cardboard box with 10 x 100 ml solvent
Cardboard box with 1 x 100 doses of lyophilisate and cardboard box with 1 x 200 ml solvent
Cardboard box with 10 x 100 doses of lyophilisate and cardboard box with 10 x 200 ml solvent

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 Ireland Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10996/278/001

8. DATE OF FIRST AUTHORISATION

08/11/2019

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

01/02/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).