SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Lawsonia ID lyophilisate and solvent for emulsion for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 0.2 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):
Paraffin, light liquid 8.3 mg
Dl-α-tocopheryl acetate 0.6 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.

This vaccine is intended for intradermal administration only.
The lyophilisate must be reconstituted in the dedicated “Solvent for Porcilis Lawsonia ID” or in Porcilis PCV ID following the instructions given in section 4.9.

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 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.

Special precautions for the protection of the environment:

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Very common (>1 animal / 10 animals treated):	Elevated temperature[1] and injection site swelling [2]

[1] Mean increase of 0.1 °C, up to 1.4 °C in individual pigs. The animals return to normal temperature within 1 day after vaccination.
[2] Mean diameter of approximately 1 cm, in individual pigs up to 5 cm. Injection site swelling disappear within 4 weeks after vaccination.

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

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 interaction

Safety and efficacy data, except for protection against mortality, are available in pigs from 3 weeks of age onwards which demonstrate that this vaccine can be administered mixed with Porcilis PCV ID and/or non-mixed with Porcilis M Hyo ID ONCE and/or non-mixed with Porcilis PRRS providing that administration site of vaccines is separated by at least 3 cm. The product literature of Porcilis PCV ID, Porcilis M Hyo ID ONCE and Porcilis PRRS should be consulted. Adverse reactions are as described in section 4.6, except for local injection site reactions where a maximum size of up to 7 cm may occur in individual pigs. Local reactions are very commonly accompanied by redness and crusts and disappear within 6 weeks after vaccination.

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

Intradermal use.

Reconstitute the lyophilisate in the solvent or in Porcilis PCV ID as follows:

Lyophilisate	Solvent for Porcilis Lawsonia ID or Porcilis PCV ID
50 doses	10 ml
100 doses	20 ml

For proper reconstitution and correct administration, use the following procedure:
1. Allow the solvent or Porcilis PCV ID to reach room temperature and shake well before use.
2. Add approximately 5-10 ml of the solvent or Porcilis PCV ID to the lyophilisate vial 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 ID. 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.

Avoid introduction of a contamination by multiple broaching.

Dosage:
A single dose of 0.2 ml of reconstituted vaccine in pigs starting at 3 weeks of age.

Vaccinate pigs by the intradermal route using a multi-dose needle-free injection device for intradermal application of liquids suitable to deliver a “jet-stream” volume of vaccine (0.2ml ± 10%) through the epidermal layers of the skin.
Safety and efficacy of Porcilis Lawsonia ID have been demonstrated using the device IDAL.

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 were observed after the administration of a double dose of Porcilis Lawsonia ID reconstituted in solvent.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated bacterial vaccines (including mycoplasma, toxoid and chlamydia) lawsonia.
ATCvet 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:
Paraffin, light liquid
Dl-α-tocopheryl acetate
Polysorbate 80
Simeticone
Sodium chloride
Potassium chloride
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
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 ID” or the vaccine specified in section 4.8.

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:
Hydrolytic glass Type I vial of 10 ml closed with nitryl rubber stoppers and sealed with aluminium caps.
PET (polyethylene terephthalate) vials of 20 ml closed with nitryl rubber stoppers and sealed with aluminium caps.

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

Cardboard box with 1 x 100 doses of lyophilisate and cardboard box with 1 x 20 ml solvent
Cardboard box with 10 x 100 doses of lyophilisate and cardboard box with 10 x 20 ml solvent

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 or household waste.

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
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 06376/5006

9. DATE OF FIRST AUTHORISATION

23 December 2020

10. DATE OF REVISION OF THE TEXT

October 2024

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

Gavin Hall

Approved 16 October 2024