# 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:**

| **Qualitative composition of excipients and other constituents** |
|---|
| **Lyophilisate:** |
| Sodium chloride |
| Potassium chloride |
| Disodium phosphate dihydrate |
| Potassium dihydrogen phosphate |
| Water for injections |
| **Solvent:** |
| Polysorbate 80 |
| Simeticone |
| Sodium chloride |
| Potassium chloride |
| Disodium phosphate dihydrate |
| Potassium dihydrogen phosphate |
| 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.
Duration of immunity: 21 weeks.

### 3.3 Contraindications

None.

### 3.4 Special warnings

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 or in Porcilis PCV M Hyo ID following the instructions given in section 3.9.

### 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<br>(>1 animal / 10 animals treated): | Elevated temperature [(1)], injection site swelling [(2)] |

[(1)] Mean increase 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 1cm, in individual pigs up to 5 cm. Injection site swelling disappears 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 the package leaflet for respective contact details.

### 3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy and lactation. However, the vaccine is recommended for single use only (see section 3.9).

### 3.8 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 (intradermal route) providing that administration sites of vaccines are separated by at least 3 cm.
Adverse events are as described in section 3.6, except for injection site swelling where a maximum size of up to 7 cm may occur in individual pigs. Injection site swellings are very commonly accompanied by redness and crusts and disappear within 6 weeks after vaccination. Lying down and malaise can be uncommonly observed in vaccinated pigs. Elevated temperatures (mean 0.3 °C, individual pigs up to 1.2 °C) may commonly occur on the day of vaccination. The animals return to normal 1 to 2 days after the peak temperature is observed. The product literature of Porcilis PCV ID, Porcilis M Hyo ID ONCE and Porcilis PRRS should be consulted.

Single-use safety and efficacy data are available in pigs from 3 weeks of age onwards which demonstrate that this vaccine can be mixed and administered with Porcilis PCV M Hyo ID and/or non-mixed with Porcilis PRRS. The administration site of non-mixed vaccines should be separated by approximately 3 cm. Adverse events are as described in section 3.6, except for injection site swellings with a maximum diameter 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 Porcilis PRRS 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

Intradermal use.

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

| Lyophilisate | Solvent for Porcilis Lawsonia ID, or Porcilis PCV ID or Porcilis PCV M Hyo ID |
|---|---|
| 50 doses | 10 ml |
| 100 doses | 20 ml |
| 200 doses | 40 ml |

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

1. Allow the solvent, or Porcilis PCV ID or Porcilis PCV M Hyo ID to reach room temperature and shake well before use.
2. Add approximately 5-10 ml of the solvent, or Porcilis PCV ID or Porcilis PCV M Hyo 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 with Porcilis PCV ID or with Porcilis PCV M Hyo 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 (0.2 ml ± 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.

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

No adverse events other than the local reactions described in section 3.6 were observed after the administration of a double dose of Porcilis Lawsonia ID reconstituted in solvent.

### 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 the lyophilisate with any other veterinary medicinal product, except the recommended "Solvent for Porcilis Lawsonia ID" or except the vaccines 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, 100 doses or 200 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 or 40 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

Cardboard box with 1 x 200 doses of lyophilisate and cardboard box with 1 x 40 ml solvent
Cardboard box with 10 x 200 doses of lyophilisate and cardboard box with 10 x 40 ml solvent
Not all pack sizes may be marketed.

### 5.5 Special precautions for the disposal of unused veterinary medicinal products 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 products 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

## 7. MARKETING AUTHORISATION NUMBER(S)

## 8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

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

{MM/YYYY}

## 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).

# LABELLING AND PACKAGE LEAFLET

# A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Cardboard box with lyophilisate**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Lawsonia ID
Lyophilisate for emulsion for injection

## 2. STATEMENT OF ACTIVE SUBSTANCES

Inactivated *Lawsonia intracellularis*: ≥ 5323 U/dose

## 3. PACKAGE SIZE

1 x 50 doses
1 x 100 doses
1 x 200 doses
10 x 50 doses
10 x 100 doses
10 x 200 doses

## 4. TARGET SPECIES

Pigs

## 5. INDICATIONS

## 6. ROUTES OF ADMINISTRATION

Intradermal use.

## 7. WITHDRAWAL PERIODS

Withdrawal periods: Zero days.

## 8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 6 hours.

## 9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator. Do not freeze.
Protect from light.

## 10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

## 11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

## 12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

## 13. NAME OF THE MARKETING AUTHORISATION HOLDER

## 14. MARKETING AUTHORISATION NUMBERS

## 15. BATCH NUMBER

Lot {number}

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Cardboard box with solvent**

## 1. NAME OF THE SOLVENT

Solvent for Porcilis Lawsonia ID

## 2. STATEMENT OF ACTIVE SUBSTANCES

Per 0.2 ml:
Paraffin, light liquid: 8.3 mg
Dl-α-tocopheryl acetate: 0.6 mg

## 3. PACKAGE SIZE

1 x 10 ml
1 x 20 ml
1 x 40 ml
10 x 10 ml
10 x 20 ml
10 x 40 ml

## 4. TARGET SPECIES

## 5. INDICATIONS

## 6. ROUTES OF ADMINISTRATION

## 7. WITHDRAWAL PERIODS

Withdrawal periods: Zero days.

## 8. EXPIRY DATE

Exp. {mm/yyyy}

## 9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator. Do not freeze.
Protect from light.

## 10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use

## 11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

## 12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

## 13. NAME OF THE MARKETING AUTHORISATION HOLDER

## 14. MARKETING AUTHORISATION NUMBERS

## 15. BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Label for lyophilisate (glass vials)**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Lawsonia ID

## 2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

*L. intracellularis* ≥ 5323 U/dose

50 doses
100 doses
200 doses

## 3. BATCH NUMBER

Lot {number}

## 4. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 6 hours.

**MINIMUM PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING (LABEL) OF THE SOLVENT**
Glass or PET vials

## 1. NAME OF THE SOLVENT

Solvent for Porcilis Lawsonia ID

## 2. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml
20 ml
40 ml

## 3. BATCH NUMBER

Lot {number}

## 4. EXPIRY DATE

Exp. {mm/yyyy}

# B. PACKAGE LEAFLET

# PACKAGE LEAFLET:

## 1. Name of the veterinary medicinal product

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

## 2. Composition

Each dose of 0.2 ml reconstituted vaccine contains:

**Active substances (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. |

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

## 3. Target species

Pigs.

## 4. Indications for use

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.

## 5. Contraindications

None.

## 6. Special warnings

Special warnings:

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 or in Porcilis PCV M Hyo ID following the instructions given in section on “Dosage for each species, route(s) and method of administration”.

Special precautions for safe use in the target 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.

Pregnancy and lactation:
Can be used during pregnancy and lactation. However, the vaccine is recommended for single use only (see section “Dosage for each species, routes and method of administration”).

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

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 (intradermal route) providing that administration sites of vaccines are separated by at least 3 cm. Adverse events are as described in section on “Adverse events”, except for injection site swelling where a maximum size of up to 7 cm may occur in individual pigs. All injection site swellings are very commonly accompanied by redness and crusts and disappear within 6 weeks after vaccination. Lying down and malaise can be uncommonly observed in vaccinated pigs. Elevated temperatures (mean 0.3 °C, individual pigs up to 1.2 °C) may commonly occur on the day of vaccination. The animals return to normal 1 to 2 days after the peak temperature is observed. The product literature of Porcilis PCV ID, Porcilis M Hyo ID ONCE and Porcilis PRRS should be consulted.

Single-use safety and efficacy data are available in pigs from 3 weeks of age onwards which demonstrate that this vaccine can be mixed and administered with Porcilis PCV M Hyo ID and/or non-mixed with Porcilis PRRS. The administration site of non-mixed vaccines should be separated by approximately 3 cm. Adverse events are as described in section “Adverse events”, except for injection site swellings with a maximum diameter 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 Porcilis PRRS 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.

Overdose:
No adverse events other than the local reactions described in the section “Adverse events” were observed after the administration of a double dose of Porcilis Lawsonia ID reconstituted in solvent.

Major incompatibilities:

Do not mix the lyophilisate with any other veterinary medicinal product, except the recommended "Solvent for Porcilis Lawsonia ID" or except the vaccines mentioned in section above.

## 7. Adverse events

Pigs:

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

[(1)] Mean increase 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 disappears within 4 weeks after vaccination.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system.

## 8. Dosage for each species, routes and method of administration

Intradermal use.

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

| Lyophilisate | Solvent for Porcilis Lawsonia ID, or Porcilis PCV ID or Porcilis PCV M Hyo ID |
|---|---|
| 50 doses | 10 ml |
| 100 doses | 20 ml |
| 200 doses | 40 ml |

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

1. Allow the solvent or Porcilis PCV ID or Porcilis PCV M Hyo ID to reach room temperature and shake well before use.
2. Add approximately 5-10 ml of the solvent or Porcilis PCV ID or Porcilis PCV M Hyo 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 with Porcilis PCV ID or with Porcilis PCV M Hyo 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 (0.2 ml ± 10%) through the epidermal layers of the skin.

Safety and efficacy of Porcilis Lawsonia ID have been demonstrated using the device IDAL.

## 9. Advice on correct administration

Appearance after reconstitution: homogenous white to nearly white emulsion after shaking.

## 10. Withdrawal periods

Zero days.

## 11. Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
Shelf life after reconstitution according to directions: 6 hours.

## 12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal products or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

## 13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

## 14. Marketing authorisation and pack sizes

Pack sizes:
Cardboard box with 1 or 10 x 50 doses of lyophilisate and cardboard box with 1 or 10 x 10 ml solvent.
Cardboard box with 1 or 10 x 100 doses of lyophilisate and cardboard box with 1 or 10 x 20 ml solvent.
Cardboard box with 1 or 10 x 200 doses of lyophilisate and cardboard box with 1 or 10 x 40 ml solvent.

Not all pack sizes may be marketed.

## 15. Date on which the package leaflet was last revised

{MM/YYYY}

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

## 16. Contact details

Marketing authorisation holder:

Manufacturer responsible for batch release:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Local representatives and contact details to report suspected adverse events:

## 17. Other information