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 ≥ 5360 U[1]

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

Adjuvant (solvent):

Light mineral oil	0.268 ml
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)

In laboratory studies and field trials:
An increase in body temperature very commonly occurs (mean ±1°C, in individual pigs up to 2.5°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.

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 interaction

Safety and efficacy data are available in pigs from 3 weeks of age onwards which demonstrate that this vaccine can be mixed with Porcilis PCV M Hyo. The product literature of Porcilis PCV M Hyo should be consulted.

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 those mentioned in section 4.6 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. 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 the inactivated 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: 2 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 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 + cardboard box with 1 x 100 ml solvent
Cardboard box with 10 x 50 doses of vaccine + cardboard box with 10 x 100 ml solvent

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

Cardboard box with 1 x 50 doses of vaccine
Cardboard box with 10 x 50 doses of vaccine

Cardboard box with 1 x 100 doses of vaccine
Cardboard box with 10 x 100 doses of vaccine

Cardboard box with 1 x 100 ml solvent*
Cardboard box with 10 x 100 ml solvent*

Cardboard box with 1 x 200 ml solvent*
Cardboard box with 10 x 200 ml solvent*

Not all pack sizes may be marketed.
*if allowed by national regulations in the Member State.

6.6 Special precautions for the disposal of unused veterinary medicinal product 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 International BV as represented by national companies in the Member States
Wim de Körverstraat 35
5831 AN Boxmeer
The NETHERLANDS

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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

10. DATE OF REVISION OF THE TEXT

{MM/YYYY}

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

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
Lyophilisate for emulsion for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Inactivated *Lawsonia intracellularis*: ≥ 5360 U/dose

3. PHARMACEUTICAL FORM

Lyophilisate for emulsion for injection

4. PACKAGE SIZE

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

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental self-injection is dangerous.

10. EXPIRY DATE

EXP {month/year}
Once reconstituted use within 6 hours.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Intervet International BV as represented by national companies in the Member States
5831 AN Boxmeer
The NETHERLANDS
[*to be completed nationally*]

16. MARKETING AUTHORISATION NUMBER(S)

{EU/0/00/000/000}

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box with solvent

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solvent for Porcilis Lawsonia

2. STATEMENT OF ACTIVE SUBSTANCES

Per 2 ml:
Light mineral oil: 0.268 ml
Aluminium (as hydroxide): 2.0 mg

3. PHARMACEUTICAL FORM

Solvent for Porcilis Lawsonia

4. PACKAGE SIZE

1 x 100 ml
1 x 200 ml
10 x 100 ml
10 x 200 ml

5. TARGET SPECIES

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental self-injection is dangerous.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Intervet International BV as represented by national companies in the Member States
5831 AN Boxmeer
The NETHERLANDS
[*to be completed nationally*]

16. MARKETING AUTHORISATION NUMBER(S)

{EU/0/00/000/000}

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label for lyophilisate

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Lawsonia [*pictogram of a pig*]

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

L. intracellularis ≥ 5360 U/dose

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 doses
100 doses

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once reconstituted use within 6 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (LABEL) OF THE SOLVENT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solvent for Porcilis Lawsonia

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

100 ml
200 ml

3. ROUTE(S) OF ADMINISTRATION

Read package leaflet before use.

4. STORAGE CONDITIONS

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

5. BATCH NUMBER

Lot {number}

6. EXPIRY DATE

EXP {month/year}

7. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Porcilis Lawsonia lyophilisate and solvent for emulsion for injection for pigs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
The national representative of
Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Manufacturer responsible for batch release
Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Lawsonia lyophilisate and solvent for emulsion for injection for pigs

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each dose of 2 ml reconstituted vaccine contains:

Active substances (lyophilisate):
Inactivated *Lawsonia intracellularis* strain SPAH-08 ≥ 5360 U[1]

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

Adjuvant (solvent):

Light mineral oil	0.268 ml
Aluminium (as hydroxide)	2.0 mg.

4. INDICATION(S)

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. ADVERSE REACTIONS

In laboratory studies and field trials:

An increase in body temperature very commonly occurs (mean ±1°C, in individual pigs up to 2.5°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.

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).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Pigs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

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.

9. ADVICE ON CORRECT ADMINISTRATION

Before use allow the solvent to reach room temperature.
Avoid introduction of contamination by multiple broaching.

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

10. WITHDRAWAL PERIOD(S)

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.
Shelf life after reconstitution according to directions: 6 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.

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.

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

Interaction with other medicinal products and other forms of interaction:
Safety and efficacy data are available in pigs from 3 weeks of age onwards which demonstrate that this vaccine can be mixed with Porcilis PCV M Hyo. The product literature of Porcilis PCV M Hyo should be consulted.

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 reactions other than those that were observed after the administration of a double dose of Porcilis Lawsonia reconstituted in Porcilis PCV M Hyo.

Incompatibilities:
Do not mix the lyophilisate with any other veterinary medicinal product, except the recommended "Solvent for Lawsonia" or the inactivated vaccine specified in the section above regarding "Method of administration".

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

The vaccine stimulates active immunity against *Lawsonia intracellularis* in pigs.

Pack sizes:
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.

Cardboard box with 1 x 50 doses of vaccine.
Cardboard box with 10 x 50 doses of vaccine.

Cardboard box with 1 x 100 doses of vaccine.
Cardboard box with 10 x 100 doses of vaccine.

Cardboard box with 1 x 100 ml solvent*.
Cardboard box with 10 x 100 ml solvent*.

Cardboard box with 1 x 200 ml solvent*.
Cardboard box with 10 x 200 ml solvent*.

Not all pack sizes may be marketed.
* if allowed by national regulations in the Member States.