

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 AND OTHER SUBSTANCES

Inactivated *Lawsonia intracellularis*: ≥ 5323 U/dose

3. PACKAGE SIZE

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

4. TARGET SPECIES

Pigs

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Intradermal use.

7. WITHDRAWAL PERIOD(S)

Withdrawal period: 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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor
Walton, Milton Keynes
MK7 7AJ

14. MARKETING AUTHORISATION NUMBERS

Vm 01708/5074

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

Accidental self-injection is dangerous.

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

Disposal: read package leaflet

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE
--

POM-V

 To be supplied only on veterinary prescription.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Cardboard box with solvent

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solvent for Porcilis Lawsonia ID

2. STATEMENT OF AND OTHER 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

10 x 10 ml

10 x 20 ml

4. TARGET SPECIES

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

7. WITHDRAWAL PERIODS

Withdrawal period: 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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor
Walton, Milton Keynes
MK7 7AJ

14. MARKETING AUTHORISATION NUMBERS

Vm 01708/5074

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

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

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

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. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

L. intracellularis ≥ 5323 U/dose

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

EXP {mm/yyyy}

Once reconstituted use within 6 hours.

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

50 doses

100 doses

6. ROUTE(S) OF ADMINISTRATION

Intradermal use.

7. WITHDRAWAL PERIOD

Zero days.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Glass or PET vials

1. NAME OF THE DILUENT/SOLVENT

Solvent for Porcilis Lawsonia ID

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

10 ml

20 ml

3. ROUTES 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.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

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 $\geq 5323 \text{ U}^1$

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 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:

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

Special precautions for the protection of the environment:

Not applicable.

Interactions 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.

The product literature of Porcilis PCV ID, Porcilis M Hyo ID ONCE and Porcilis PRRS should be consulted.

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.

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.

Overdose:

No adverse events other than the local reactions described in the section “Adverse reactions” 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 the vaccine specified in the paragraph above regarding “Interaction with other medicinal products and other forms of interaction”.

7. ADVERSE EVENTS

Pigs:

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

¹Mean increase of 0.1 °C, up to 1.4 °C in individual pigs. The animals return to normal temperature within 1 day after vaccination.

²Mean 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 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 local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

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

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 (0.2 ml \pm 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 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. 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.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

Ask your veterinary surgeon 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

Marketing authorisation numbers:

Vm 01708/5074

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.

Not all pack sizes may be marketed.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

September 2023

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

16. CONTACT DETAILS

Marketing authorisation holder:

MSD Animal Health UK Ltd.
Walton Manor
Walton, Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release:

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Contact details to report suspected adverse reactions:

MSD Animal Health UK Ltd.
Tel.: +44 (0)1908 685685

Distributor in Northern Ireland:


Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road, Dublin 24
Ireland

17. OTHER INFORMATION

For animal treatment only.

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

☒ POM-V To be supplied only on veterinary prescription.

A handwritten signature in black ink, consisting of several loops and a long horizontal stroke at the end.

Approved 18 October 2023