LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX with lyophilizate

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Lawsonia 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
10 x 50 doses
10 x 100 doses

4. TARGET SPECIES

Pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular 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 OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 01708/3032

15. 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: 222.4 mg
Aluminium (as hydroxide): 2.0 mg

3. PACKAGE SIZE

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

4. TARGET SPECIES

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIOD(S)

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 OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 01708/3032

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL Glass vial for lyophilisate

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Lawsonia

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

L. intracellularis ≥ 5323 U/dose

50 doses
100 doses

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

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

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (LABEL) OF THE SOLVENT (Normal sized bottles of 100 ml and 200 ml)

PET BOTTLE

1. NAME OF THE SOLVENT

Solvent for Porcilis Lawsonia

100 ml
200 ml

2. TARGET SPECIES

Pigs

3. ROUTE(S) OF ADMINISTRATION

Read package leaflet before use.

4. EXPIRY DATE

EXP {mm/yyyy}

5. SPECIAL STORAGE PRECAUTIONS

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

6. NAME OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited

7. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Porcilis Lawsonia lyophilisate and solvent for emulsion for injection for pigs

2. Composition

Each dose of 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):

Light mineral oil	222.4 mg
Aluminium (as hydroxide)	2.0 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.

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.

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 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, 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.

Overdose:
No adverse reactions other than the local reactions described under the section “Adverse events” and the temperature increases described under the section “Interaction with other medicinal products and other forms of interaction” were observed after the administration of a double dose of Porcilis Lawsonia reconstituted in Porcilis PCV M Hyo.

Major incompatibilities:
Do not mix with any other veterinary medicinal product, except the recommended “Solvent for Porcilis Lawsonia” or except those mentioned above.

7. 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 (severe allergic) 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 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 using the contact details at the end of this leaflet, or via your national reporting system:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes 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

Avoid introduction of contamination by multiple broaching.
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 after EXP. 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 product 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 how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 01708/3032

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

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
MK7 7AJ
United Kingdom

Manufacturer responsible for batch release

Intervet International B.V.

Wim de Körverstraat 35

Boxmeer

5831 AN
The Netherlands

15. Other information

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

Approved: 18 June 2024

Gavin Hall