

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis PCV M Hyo emulsion for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per 2 ml:

| | |
|-------------------------------|------------|
| PCV2 ORF2 subunit antigen | ≥ 2 828 AU |
| <i>M. hyopneumoniae</i> inac. | ≥ 2.69 RPU |

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

3. PACKAGE SIZE

20 ml
50 ml
100 ml
200 ml
500 ml
10x20 ml
10x50 ml
10x100 ml
10x200 ml
10x500 ml

4. TARGET SPECIES

Pigs for fattening

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 8 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not freeze.
Protect from direct sunlight.

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 Ltd.

14. MARKETING AUTHORISATION NUMBERS

Vm 01708/5056

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

Accidental administration 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 Veterinary medicinal product subject to prescription.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vials of 100, 200 and 500 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis PCV M Hyo emulsion for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per 2 ml:

PCV2 ORF2 subunit antigen $\geq 2\ 828$ AU
M. hyopneumoniae inac. ≥ 2.69 RPU

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

100 ml
200 ml
500 ml

3. TARGET SPECIES

Pigs (for fattening)

4. ROUTES OF ADMINISTRATION

Intramuscular use. Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 8 hours.

7. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not freeze.
Protect from direct sunlight.
Keep the vial in the outer carton.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.

9. BATCH NUMBER

Lot {number}

10. SPECIAL WARNING(S), IF NECESSARY

Accidental administration is dangerous.

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

Disposal: Read package leaflet.

12. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.

POM-V Veterinary medicinal product subject to prescription.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vials of 20 and 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis PCV M Hyo



2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Per 2 ml:
PCV2 ORF2 subunit antigen $\geq 2\ 828$ AU
M. hyopneumoniae inac. ≥ 2.69 RPU

20 ml
50 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 8 hours.

5. ROUTE(S) OF ADMINISTRATION

Intramuscular use.

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis PCV M Hyo emulsion for injection for pigs

2. COMPOSITION

2 ml contains:

Active substances:

| | |
|---|-------------------------|
| Porcine circovirus type 2 (PCV2) ORF2 subunit antigen | ≥ 2 828 AU ¹ |
| <i>Mycoplasma hyopneumoniae</i> J strain inactivated | ≥ 2.69 RPU ² |

Adjuvants:

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

¹ Antigenic units as determined in the in vitro potency test (ELISA).

² Relative potency units defined against a reference vaccine.

Homogenous white to nearly white emulsion after shaking.

3. TARGET SPECIES

Pigs (for fattening)

4. INDICATIONS FOR USE

For the active immunisation of pigs to reduce viraemia, virus load in lungs and lymphoid tissues, virus shedding caused by porcine circovirus type 2 (PCV2) infection, and severity of lung lesions caused by *Mycoplasma hyopneumoniae* infection. To reduce the loss of daily weight gain during the finishing period in face of infections with *Mycoplasma hyopneumoniae* and/or PCV2 (as observed in field studies).

Onset of immunity with single dose vaccination:

PCV2: 2 weeks after vaccination

M. hyopneumoniae: 4 weeks after vaccination

Onset of immunity with two dose vaccination:

PCV2: 18 days after the first vaccination

M. hyopneumoniae: 3 weeks after the second vaccination

Duration of immunity (both vaccination schedules):

PCV2: 22 weeks after (the last) vaccination

M. hyopneumoniae: 21 weeks after (the last) 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.

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 Lawsonia and/or Porcilis PRRS. When Porcilis PCV M Hyo is given at the same time with Porcilis Lawsonia, 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 Lawsonia 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 data available.

Major incompatibilities:

Do not mix with any other veterinary medicinal product, except Porcilis Lawsonia.

7. ADVERSE EVENTS

Pigs for fattening:

| | |
|---|--|
| Very common (>1 animal / 10 animals treated): | Elevated temperature ¹ |
| Uncommon (1 to 10 animals / 1,000 animals treated): | Injection site swelling ² Decreased activity ³ Lying down ³ Uncomfortable ³ |
| Rare (1 to 10 animals / 10,000 animals treated): | Hypersensitivity reaction ⁴ |
| Very rare (<1 animal / 10,000 animals treated, including isolated reports): | Anaphylactic type reaction ⁵ |

¹ On the day of vaccination (mean ± 1 °C, in individual pigs up to 2 °C). The animals return to normal from 1 to 2 days after the peak temperature is observed.

² < 2 cm diameter. These reactions disappear within 12 days after the first vaccination of the two-dose vaccination schedule and within 3 days after completion of either the single or the two-dose vaccination schedule.

³ Up to one day after vaccination.

⁴ After the first vaccination of the two-dose vaccination schedule.

⁵ For the single dose vaccination: May be life threatening. 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 holder using the contact details at the end of this leaflet, or via your national reporting system:

E-mail: adverse.events@vmd.gov.uk

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>.

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Vaccinate pigs by the intramuscular route in the neck.

Single dose vaccination schedule:

A single dose of 2 ml in pigs starting at 3 weeks of age.

Two dose vaccination schedule:

Two injections each of 1 ml in pigs starting at 3 days of age with an interval of at least 18 days.

Needle length and diameter should be adapted to the age of the animal.

When PCV2 and/or *M. hyopneumoniae* infections occur early the two-dose vaccination schedule is recommended.

Mixed use with Porcilis Lawsonia

The Porcilis PCV M Hyo emulsion may be used to reconstitute Porcilis Lawsonia lyophilisate shortly before vaccination in pigs from 3 weeks of age onwards as follows:

| Porcilis Lawsonia lyophilisate | Porcilis PCV M Hyo |
|--------------------------------|--------------------|
| 50 doses | 100 ml |
| 100 doses | 200 ml |

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

1. Allow Porcilis PCV M Hyo to reach room temperature and shake well before use.
2. Add 5 - 10 ml Porcilis PCV M Hyo to the Porcilis Lawsonia lyophilisate and mix briefly.
3. Withdraw the reconstituted concentrate from the vial and inject it back into the vial with Porcilis PCV M Hyo. Shake briefly to mix.
4. Use the vaccine mixture within 6 hours of reconstitution. Any vaccine remaining at the end of this time should be discarded.

Dosage:

A single dose (2 ml) of Porcilis Lawsonia mixed with Porcilis PCV M Hyo is given intramuscularly in the neck.

Visual appearance after reconstitution: homogenous white to nearly white emulsion after shaking.

9. ADVICE ON CORRECT ADMINISTRATION

Before using the vaccine allow it to reach room temperature (15 °C - 25 °C) and shake well before use.

Avoid introduction of contamination.

10. WITHDRAWAL PERIODS

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a refrigerator (2 °C - 8 °C).

Do not freeze.

Protect from direct sunlight.

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 first opening the immediate packaging: 8 hours.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicine should not be disposed of via wastewater.
Ask your veterinary surgeon how to dispose of medicines no longer required.
These measures should help to protect the environment.

13. 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.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 01708/5056

Cardboard box with 1 or 10 vials of 20, 50, 100, 200 or 500 ml.

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:
MSD Animal Health UK Limited
Walton Manor, Walton
Milton Keynes
MK7 7AJ, UK

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

17. OTHER INFORMATION

The vaccine stimulates active immunity against porcine circovirus type 2 and *Mycoplasma hyopneumoniae* in pigs.

POM-V Veterinary medicinal product subject prescription.

For animal treatment only.

A handwritten signature in black ink, consisting of several loops and a long horizontal stroke extending to the right.

Approved 19 April 2024