LABELLING AND PACKAGE LEAFLET

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis M Hyo ID ONCE emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

M. hyopneumoniae inactivated, strain 11: ≥ 6.5 $\log_2$ Ab titre/dose

3. PACKAGE SIZE

50 doses
5 x 50 doses
10 x 50 doses
100 doses
5 x 100 doses
10 x 100 doses

4. TARGET SPECIES

Pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intradermal use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp.{mm/yyyy}
Once broached use within 3 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.
Walton Manor, Walton
Buckinghamshire
Milton Keynes
MK7 7AJ

14. MARKETING AUTHORISATION NUMBERS

Vm 01708/3009

15. BATCH NUMBER

Lot {number}

In accordance with Article 13 of Reg 2019/6, the following additional information is proposed:

Accidental injection is dangerous.

Disposal: Read package leaflet.

To be supplied only veterinary prescription.

POM-V

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis M Hyo ID ONCE

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

≥ 6.5 log_2 Ab titre inact. *M. hyopneumoniae*/dose

50 doses
100 doses

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 3 hours.

In accordance with Article 13 of Reg 2019/6, the following additional information is proposed:

For animal treatment only.

Withdrawal period: Zero days.

POM-V

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Porcilis M Hyo ID ONCE emulsion for injection for pigs

2. Composition

Each dose of 0.2 ml contains:

Active substance:
Mycoplasma hyopneumoniae inactivated, strain 11: ≥ 6.5 $\log_2$ Ab titre*

* Mean antibody titre (Ab) obtained after inoculation of mice with a 1/1000 pig dose.

Adjuvant:
Light liquid paraffin: 34.6 mg
dl-α-tocopheryl acetate: 2.5 mg

White to nearly white emulsion with creamy appearance after shaking.

3. Target species

Pigs.

4. Indications for use

For the active immunisation of pigs to reduce pulmonary lesions and the decrease in daily weight gain during the finishing period due to infection caused by *Mycoplasma hyopneumoniae*.

Onset of immunity: 3 weeks after vaccination.
Duration of immunity: 22 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.

Interactions 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 administered on the same day, but non-mixed with Porcilis PRRS (intradermal route) and/or non-mixed with Porcilis PCV ID or with Porcilis PCV ID mixed with Porcilis Lawsonia ID providing that non-mixed administration sites of vaccines are separated by at least 3 cm. Adverse events are as described in section “Adverse events”, except for injection site swelling where a maximum size of up to 6 cm may occur in individual pigs. Injection site swellings may last 8 weeks and are very commonly accompanied by redness and crusts. In the event that the crust is rubbed off, some small skin damage may be commonly observed. The product information of Porcilis PCV ID, Porcilis Lawsonia 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 reactions other than those mentioned under section on adverse reactions have been observed after administration of a double dose. However, these reactions may be more pronounced. A mean transient temperature increase of 1 °C may be observed. Injection site swelling may be observed with a maximum diameter of up to 7 cm. The injection site swelling disappear completely within approximately 9 weeks after vaccination.

Major incompatibilities:
Do not mix with any other veterinary medicinal products.

7. Adverse events

Pigs:

Very common (>1 animal / 10 animals treated):	Elevated temperature[1], injection site swelling[2]
Uncommon (1 to 10 animals / 1,000 animals treated):	Lying down, malaise

[1]A transient elevated temperature (mean 0.7 °C, in individual pigs up to 2 °C) very commonly occurs on the day of vaccination. The animals return to normal 1 to 2 days after the peak temperature is observed

[2]A transient injection site swelling mostly consisting of hard non-painful button-like swellings of a diameter of up to 4 cm can be very commonly observed. In individual pigs redness and/or a biphasic pattern of the injection site swelling, consisting of an increase and decrease followed by another increase and decrease of the size, may be observed. The injection site swelling disappears completely within approximately 7 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 the local representative of 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

Intradermal use.

Intradermal administration of 0.2 ml per animal preferably at the sides of the neck or along the muscles of the back 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. A small, transient, intradermal lump observed after the intradermal application is indicative of the appropriate vaccination technique.
Safety and efficacy of Porcilis M Hyo ID ONCE have been demonstrated using the device IDAL.

<u>Vaccination scheme:</u>
Vaccinate once from an age of 2 weeks onwards.

9. Advice on correct administration

Before using the vaccine allow it to reach room temperature (15 - 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).
It has been demonstrated that transport at 30 °C for 3 days has no impact on the quality of the product. Do not freeze.
Protect from direct sunlight.

Do not use this veterinary medicinal product after the expiry date which is stated on the label/carton. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 3 hours.

12. Special precautions for disposal

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

13. Classification of veterinary medicinal product

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 01708/3009

Cardboard box with 1, 5, 10 glass vial(s) of 10 ml (50 doses), or 20 ml (100 doses)
Cardboard box with 1, 5, 10 PET vial(s) of 20 ml (100 doses)

Vials are closed with a nitrile rubber stopper (type I, Ph. Eur.) and sealed with a coded aluminium cap.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

January 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:
Intervet Ireland Ltd.
Tel.: +353 (0)1 2970220

Distributor in Northern Ireland:
Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road, Dublin 24
Ireland

17. Other information

For animal treatment only.

Approved 08 September 2023