

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis M Hyo ID ONCE emulsion for injection for pigs

IT: Porsilis M Hyo ID ONCE

HU: Porcilis M Hyo ID ONCE vakcina A.U.V.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 0.2 ml contains:

Active substance:

Mycoplasma hyopneumoniae inactivated, strain 11: $\geq 6.5 \log_2$ Ab titre*

* Mean antibody titre (Ab) obtained after inoculation of mice with a 1/1,000 pig dose.

Adjuvants:

light liquid paraffin 34.6 mg

dl- α -tocopheryl acetate 2.5 mg

Excipients:

Qualitative composition of excipients and other constituents
Polysorbate 80
Simethicone
Disodium phosphate dihydrate
Sodium dihydrogen phosphate dihydrate
Water for injections

Emulsion for injection.

White to nearly white emulsion with creamy appearance after shaking.

3. CLINICAL INFORMATION

3.1 Target species

Pigs.

3.2 Indications for use for each target species

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.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See also the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Not applicable.

3.8 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 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 3.6, 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.

3.9 Administration routes and dosage

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 ($0.2\text{ml} \pm 10\%$) 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.

Vaccination scheme:

Vaccinate once from an age of 2 weeks onwards.

Before using the vaccine allow it to reach room temperature (15–25 °C) and shake well before use. Avoid introduction of contamination.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No adverse reactions other than those mentioned under section 3.6 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. Local reactions may be observed with a maximum diameter of up to 7 cm. The local reactions disappear completely within approximately 9 weeks after vaccination.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI09AB13

The veterinary medicinal product is an inactivated bacterial vaccine containing whole cell concentrate of *Mycoplasma hyopneumoniae* strain 11. This antigen is incorporated in an adjuvant based on a combination of light liquid paraffin and dl- α -tocopheryl acetate in order to give a prolonged stimulation of immunity. The product stimulates the development of active immunity in pigs against *Mycoplasma hyopneumoniae*.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product except those mentioned in section 3.8.

5.2 Shelf life

Shelf life of the veterinary medical product as packaged for sale: 2 years.

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

5.3 Special precautions for storage

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.

5.4 Nature and composition of immediate packaging

Cardboard box with 1 glass vial of 10 ml (50 doses)

Cardboard box with 1 glass vial of 20 ml (100 doses)

Cardboard box with 5 glass vials of 10 ml (50 doses)

Cardboard box with 5 glass vials of 20 ml (100 doses)

Cardboard box with 10 glass vials of 10 ml (50 doses)

Cardboard box with 10 glass vials of 20 ml (100 doses)

Cardboard box with 1 PET vial of 20 ml (100 doses)

Cardboard box with 5 PET vials of 20 ml (100 doses)

Cardboard box with 10 PET vials 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.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

[to be completed nationally]

7. MARKETING AUTHORISATION NUMBER(S)

[to be completed nationally]

8. DATE OF FIRST AUTHORISATION

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

[to be completed nationally]

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY}

[to be completed nationally]

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).

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: $\geq 6.5 \log_2$ Ab titre/dose**3. PACKAGE SIZE**

50 doses
5x50 doses
10x50 doses
100 doses
5x100 doses
10x100 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

[to be completed nationally]

14. MARKETING AUTHORISATION NUMBERS

[to be completed nationally]

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**Vials****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Porcilis M Hyo ID ONCE

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)** $\geq 6.5 \log_2$ 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.

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: $\geq 6.5 \log_2$ 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.

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 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 product except those mentioned in section above.

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)	Lying down, malaise

treated):	
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⁽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.

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 (0.2ml ± 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.

Vaccination scheme:

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 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 or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal product

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

[MA numbers to be completed nationally]

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 was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).

16. Contact details

Marketing authorisation holder:

[to be completed nationally]

Manufacturer responsible for batch release:

Intervet International B.V.

Wim de Körverstraat 35

5831 AN Boxmeer

The Netherlands

Local representatives and contact details to report suspected adverse reactions:

[to be completed nationally]

17. Other information

[To be completed nationally where applicable]