SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis M Hyo ID ONCE emulsion for injection for pigs

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:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection.
White to nearly white emulsion with creamy appearance after shaking.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs.

4.2 Indications for use, specifying the 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.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in 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 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.

4.6 Adverse reactions (frequency and seriousness)

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.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 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 4.6, 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.

4.9 Amount(s) to be administered and administration route

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.

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No adverse reactions other than those mentioned under section 4.6 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.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for *Suidae*; inactivated bacterial vaccines for pigs.
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*.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polysorbate 80
Simethicone
Disodium phosphate dihydrate
Sodium dihydrogen phosphate dihydrate
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal products.

6.3 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.

6.4 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.

6.5 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.

6.6 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.

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 06376/5007

9. DATE OF FIRST AUTHORISATION

24 January 2012

10. DATE OF REVISION OF THE TEXT

October 2024

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Gavin Hall

Approved 16 October 2024