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

One dose of 0.2 ml contains:
Active substance:
Inactivated whole cell concentrate of *Mycoplasma hyopneumoniae* strain 11: ≥ 6.5 $\log_2$ Ab titre*
* Mean antibody titre (Ab) obtained after inoculation of mice with a 1/1,000 pig dose.

Adjuvant:

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 (finishing pigs).

4.2 Indications for use, specifying the target species

For the active immunisation of finishing 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 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 administration with this 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.

4.6 Adverse reactions (frequency and seriousness)

A transient increase in body 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. In individual animals mild systemic reactions may be observed on the day of vaccination consisting of a tendency of the animal to lie down and minor signs of discomfort. Transient local reactions 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 local reactions, consisting of an increase and decrease followed by another increase and decrease of the size, may be observed. The local reactions disappear completely within approximately 7 weeks after vaccination.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 treated animals displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 which demonstrate that this vaccine can be given with Porcilis PCV ID at least 3 cm apart on the same day from 3 weeks of age. The possible adverse reactions are as presented in section 4.6, except for the size of the local reactions which may increase up to 6 cm in individual pigs. Redness and crusts at the local reaction may be very commonly observed. The product information of Porcilis PCV ID should be consulted.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. 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 Amounts 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 an 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.

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 1.0 °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

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Suidae; inactivated bacterial vaccines for pigs.
ATCvet code: QI09AB13.

Porcilis M Hyo ID ONCE 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

Light liquid paraffin
dl-α-tocopheryl acetate
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 product.

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 refrigerated (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 boxes with 1, 5 or 10 glass vials (type I, Ph. Eur.) containing 10 or 20 ml corresponding to 50 and 100 doses respectively.
Cardboard boxes with 1, 5 or 10 PET vials containing 20 ml corresponding to 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 product or waste materials derived from the use of such products

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

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

8. MARKETING AUTHORISATION NUMBER

Vm 01708/4562

9. DATE OF FIRST AUTHORISATION

24 January 2012

10. DATE OF REVISION OF THE TEXT

August 2020

Approved 14 August 2020

.