SPC

Porcilis® M Hyo ID ONCE

SUMMARY OF PRODUCT CHARACTERISTICS

July 2016

MSD Animal Health

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

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
None.

4.5 Special precautions for use

Special precautions for use in animals
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 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 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, 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 from each other 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 intradermal device. A small, transient, intradermal lump observed after the intradermal application is indicative of the appropriate vaccination technique.

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 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

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

Represented by the national companies in the Member States

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Cardboard box

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. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One dose of 0.2 ml contains:
≥ 6.5 $\log_2$ Ab titre* inact. whole cell concentrate of *M. hyopneumoniae*
34.6 mg light liquid paraffin
2.5 mg dl-α-tocopheryl acetate

* See package leaflet

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

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

5. TARGET SPECIES

Pigs (finishing pigs)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intradermal use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Cardboard box

9. SPECIAL WARNING(S), IF NECESSARY

Accidental self-injection is dangerous.
Read the package leaflet before use.

10. EXPIRY DATE

EXP{month/year}
Once broached use within 3 hours.

11. SPECIAL STORAGE CONDITIONS

Store refrigerated.
Do not freeze.
Protect from direct sunlight.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Intervet International BV
NL-5831 AN Boxmeer

Represented by the national companies in the Member States

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
Vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

One dose contains:
≥6.5 $\log_2$ Ab titre inact. *M. hyopneumoniae*

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 doses
100 doses

4. ROUTE(S) OF ADMINISTRATION

i.d. use

5. WITHDRAWAL PERIOD

Withdrawal period: zero days

6. BATCH NUMBER

<Batch> <Lot> {number}

7. EXPIRY DATE

EXP {month/year}
Once broached use within 3 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PORCILIS M HYO ID ONCE (IT: PORSILIS M HYO ID ONCE, HU: PORCILIS M HYO ID ONCE VAKCINA A.U.V.) EMULSION FOR INJECTION FOR PIGS

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:
Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The NETHERLANDS

Represented by the national companies in the Member States.

2. 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.

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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 1/1000 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.

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

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 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs (finishing pigs).

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 an intradermal device. A small, transient, intradermal lump observed after the intradermal application is indicative of the appropriate vaccination technique.

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 PERIOD

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.
Shelf life after first opening the container: 3 hours.

12. SPECIAL WARNING(S)

Special precautions for use in animals:
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 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.

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 different sites 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. 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.

Overdose (symptoms, emergency procedures, antidotes):
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 1.0 °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.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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.*

Pack sizes: 1, 5 or 10 vials of 50 or 100 doses.

Not all pack sizes may be marketed.