

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

20, 50, 100, 200 and 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis M Hyo, suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose of 2 ml:

≥ 7.0 log₂ Ab titre* inact. whole cell concentrate of *M. hyopneumoniae* (11)

150 mg dl-α-tocopheryl acetate

* see package leaflet

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

1x/5x/10x 10/ 25/ 50/100/125 doses (20/50/100/200/250 ml)

5. TARGET SPECIES

Pig (finishing pigs)

6. INDICATION(S)

Vaccine against *M. hyopneumoniae*

7. METHOD AND ROUTE(S) OF ADMINISTRATION

i.m. injection of 2 ml

Read the package leaflet before use

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use

10. EXPIRY DATE

EXP:

Once broached, use within 3 hours

11. SPECIAL STORAGE CONDITIONS

Store at 2°C to 8°C. Do not freeze.

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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4636

17. MANUFACTURER'S BATCH NUMBER

Lot:

POM-V

To be supplied only on veterinary prescription.

<PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE>

100, 200 and 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis M Hyo, suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose:
≥ 7.0 log₂ Ab titre inact. *M. hyopneumoniae*

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

100, 200, 250 ml (50/100/125 doses).

5. TARGET SPECIES

Pig

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

i.m. injection
Read the package leaflet before use

8. WITHDRAWAL PERIOD

Withdrawal period: zero days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use

10. EXPIRY DATE

EXP
Once broached, use within 3 hours

11. SPECIAL STORAGE CONDITIONS

Store at 2°C to 8°C. Do not freeze.

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

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only

14. THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4636

17. MANUFACTURER'S BATCH NUMBER

Lot:

POM-V

To be supplied only on veterinary prescription.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

20, 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis M Hyo

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Per dose:
≥ 7.0 log₂ Ab titre inact. *M. hyopneumoniae*

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

20, 50 ml (10/25/doses).

4. ROUTE(S) OF ADMINISTRATION

i.m. injection

5. WITHDRAWAL PERIOD

Withdrawal period: zero days

6. BATCH NUMBER

Lot.

7. EXPIRY DATE

EXP:
Once broached, use within 3 hours

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

PACKAGE LEAFLET
Porcilis M Hyo, suspension for injection

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

Marketing authorisation holder:
MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer for batch release:
Intervet International BV
represented by
Intervet UK Ltd.
Walton Manor
Walton
Milton Keynes
Bucks MK7 7AJ

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis M Hyo, suspension for injection;
IT: Porsilis M Hyo

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

Per dose of 2 ml:
Inactivated whole cell concentrate of *Mycoplasma hyopneumoniae* strain 11:
≥ 7.0 log₂ Ab titre*
Adjuvant: 150 mg dl-α-tocopheryl acetate

* Mean antibody titre (Ab) obtained after inoculation of mice with a 1/20 pig dose.

4. INDICATION(S)

For finishing pigs:
For the active immunisation of pigs to reduce pulmonary lesions due to infection by *Mycoplasma hyopneumoniae*.

Onset of immunity: 2 weeks after the second injection
Duration of immunity: at least 20 weeks after the second injection.

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

A mean transient temperature increase in body temperature of about 0.3°C, in individual pigs up to 2.0°C, may occur on the first 1 to 2 days after vaccination. The animals return to normal the next day. A transient swelling/redness (max. diameter 5 cm) may occur at the injection site diminishing over a period of maximally 14 days.
In isolated cases hypersensitivity reactions may occur.

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

7. TARGET SPECIES

Pig (finishing pigs)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Intramuscular injection of 2 ml in the neck in the area behind the ear

Vaccination scheme:

Vaccinate pigs twice with a three week interval. The first injection can be given from an age of 1 week onwards.

For simultaneous use with Porcilis PRRS in finishing pigs from 4 weeks of age (3 weeks after priming) the vaccine may be used for reconstitution shortly before vaccination.

Thereby the following instructions should be used:

Porcilis PRRS		Porcilis M Hyo
10 doses	+	20 ml
25 doses	+	50 ml
50 doses	+	100 ml
100 doses	+	200 ml

A single dose (2 ml) of Porcilis M Hyo mixed with Porcilis PRRS is given intramuscularly in the neck.

9. ADVICE ON CORRECT ADMINISTRATION

Before using the vaccine allow it to reach room temperature (15-25°C) and shake well before use.

Use sterile syringes and needles.

Avoid introduction of contamination.

10. WITHDRAWAL PERIOD

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Store in a refrigerator (2 °C – 8 °C).

Do not freeze.

Do not use after the expiry date stated on the label.

Once broached use within 3 hours

After mixing with Porcilis PRRS: use within 1 hour (at room temperature)

12. SPECIAL WARNING(S)

Vaccinate only healthy animals.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Safety and efficacy data are available in pigs from 4 weeks of age onwards, which demonstrate that this vaccine can be mixed with Porcilis PRRS.

The product literature of Porcilis PRRS should also be consulted before administration of the mixed product.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the product 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. No information is available on the safety and efficacy of the use of Porcilis M Hyo mixed with Porcilis PRRS in breeding animals or during pregnancy.

Do not mix with any other veterinary medicinal product except with Porcilis PRRS.

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

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

14. DATE ON WHICH THE PACKAGE INSERT WAS LAST APPROVED

June 2020

15. OTHER INFORMATION

Porcilis M Hyo is an inactivated bacterial vaccine containing the whole cell concentrate of *Mycoplasma hyopneumoniae* strain 11. This antigen is incorporated in an adjuvant based on 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*.

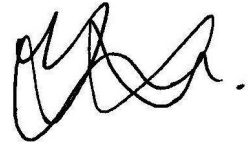
Pack sizes: 1, 5 or 10 vials of 20, 50, 100, 200 or 250 ml.

Not all pack sizes may be marketed.

Vm 01708/4636

POM-V

To be supplied only on veterinary prescription.

A handwritten signature in black ink, consisting of several loops and a final flourish.

Approved: 10 June 2020