Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis M Hyo, suspension for injection.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of 2 ml

Active substance
Inactivated whole cell concentrate of *Mycoplasma hyopneumoniae* strain 11: ≥ 7.0 $\log_2$ Ab titre

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

Adjuvant
150 mg dl-α-tocopheryl acetate

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Suspension for injection; white or nearly white.

4 CLINICAL PARTICULARS

4.1 Target Species

Pig (finishing pigs).

4.2 Indications for use, specifying the target species

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.

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 only healthy animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
In case of accidental self-injection, seek medical advice immediately and show the package insert or label to the physician.

4.6 Adverse reactions (frequency and seriousness)

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.

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 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 decided 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.

4.9 Amounts to be administered and administration route

Intramuscular injection in pigs of 2 ml per animal 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.

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.

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

No adverse reactions other than already mentioned under section “Adverse reactions” have been observed after administration of a double dose.

4.11 Withdrawal Period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated bacterial vaccine
ATCvet code: QI09AB13

Porcilis M Hyo is an inactivated bacterial vaccine containing 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.*

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

dl-α-tocopheryl acetate
Polysorbate 80
Simethicone
Sodium chloride
Sodium dihydrogen phosphate
Disodium hydrogen phosphate
Water for injection

6.2 Incompatibilities

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

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years
Shelf-life after first opening the immediate packaging: 3 hours
Shelf-life after mixing with Porcilis PRRS: 1 hour (at room temperature)

6.4 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C). Do not freeze.

6.5 Nature and composition of immediate packaging

Cardboard boxes with either 1 PET vial of 20, 50, 100, 200 or 250 ml, 5 PET vials of 20, 50, 100, 200 or 250 ml or 10 PET vials of 20, 50, 100, 200 or 250 ml.
Vials are closed with a halogenobutyl rubber stopper and 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

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

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited,
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/196/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

3rd December 2010

10 DATE OF REVISION OF THE TEXT