SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis PCV M Hyo emulsion for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

2 ml contains:

Active substances:

Porcine circovirus type 2 (PCV2) ORF2 subunit antigen	≥ 2 828 AU[1]
Mycoplasma hyopneumoniae J strain inactivated	≥ 2.69 RPU[2]

Adjuvants:

Light mineral oil	0.268 ml
Aluminium (as hydroxide)	2.0 mg

[1]Antigenic units as determined in the in vitro potency test (ELISA).
[2]Relative potency units defined against a reference vaccine.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection.
Homogenous white to nearly white emulsion after shaking.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs (for fattening).

4.2 Indications for use, specifying the target species

For the active immunisation of pigs to reduce viraemia, virus load in lungs and lymphoid tissues, virus shedding caused by porcine circovirus type 2 (PCV2) infection, and severity of lung lesions caused by *Mycoplasma hyopneumoniae* infection. To reduce the loss of daily weight gain during the finishing period in face of infections with *Mycoplasma hyopneumoniae* and/or PCV2 (as observed in field studies).

Onset of immunity with single dose vaccination:

PCV2: 2 weeks after vaccination
M. hyopneumoniae: 4 weeks after vaccination.

Onset of immunity with two dose vaccination:
PCV2: 18 days after first vaccination
M. hyopneumoniae: 3 weeks after the second vaccination.

Duration of immunity (both vaccination schedules):
PCV2: 22 weeks after (the last) vaccination
M. hyopneumoniae: 21 weeks after (the last) 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 for fattening:

Very common (>1 animal / 10 animals treated):	Elevated temperature[1]
Uncommon (1 to 10 animals / 1 000 animals treated):	Injection site swelling[2] Decreased activity[3] Lying down[3] Uncomfortable[3]
Rare (1 to 10 animals / 10 000 animals treated):	Hypersensitivity reaction[4]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Anaphylactic type reaction[5]

1 On the day of vaccination (mean ±1 °C, in individual pigs up to 2 °C). The animals return to normal from 1 to 2 days after the peak temperature is observed.
2 < 2 cm diameter. These reactions disappear within 12 days after the first vaccination of the two-dose vaccination schedule and within 3 days after completion of either the single or the two-dose vaccination schedule.
3 Up to one day after vaccination.
4 After the first vaccination of the two-dose vaccination schedule.
5 For the single dose vaccination: May be life threatening. If such reactions occur, appropriate treatment is recommended.

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 the national competent authority via the national reporting system. See section 'Contact details' of the package leaflet.

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 in pigs from 3 weeks of age onwards are available, which demonstrate that this vaccine can be given at the same time with Porcilis Lawsonia and/or Porcilis PRRS. When Porcilis PCV M Hyo is given at the same time with Porcilis Lawsonia, these products should be mixed (see section 4.9 below), whereas Porcilis PRRS should always be given at a separate site (preferably at the opposite side of the neck). The product literature of Porcilis Lawsonia and/or Porcilis PRRS should be consulted before administration.

In individual pigs the temperature increase after associated use may commonly exceed 2 °C. The temperature returns to normal from 1 to 2 days after the peak temperature is observed. Transient local injection site reactions, which are restricted to a slight swelling (maximum 2 cm diameter), may commonly occur directly after vaccination, but reactions may not appear until 12 days after vaccination. All these reactions disappear within 6 days. Hypersensitivity reactions after vaccination may

occur uncommonly.

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

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

Vaccinate pigs by the intramuscular route in the neck.

Single dose vaccination schedule:
A single dose of 2 ml in pigs starting at 3 weeks of age.

Two-dose vaccination schedule:
Two injections each of 1 ml in pigs starting at 3 days of age with an interval of at least 18 days.

Needle length and diameter should be adapted to the age of the animal.

When PCV2 and/or *M. hyopneumoniae* infections occur early the two-dose vaccination schedule is recommended.

Mixed use with Porcilis Lawsonia
The Porcilis PCV M Hyo emulsion may be used to reconstitute Porcilis Lawsonia lyophilisate shortly before vaccination in pigs from 3 weeks of age onwards as follows:

Porcilis Lawsonia lyophilisate	Porcilis PCV M Hyo
50 doses	100 ml
100 doses	200 ml

For proper reconstitution and correct administration, use the following procedure:
1. Allow Porcilis PCV M Hyo to reach room temperature and shake well before use.
2. Add 5-10 ml Porcilis PCV M Hyo to the Porcilis Lawsonia lyophilisate and mix briefly.
3. Withdraw the reconstituted concentrate from the vial and inject it back into the vial with Porcilis PCV M Hyo. Shake briefly to mix.
4. Use the vaccine mixture within 6 hours of reconstitution. Any vaccine remaining at the end of this time should be discarded.

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

Visual appearance after reconstitution: homogenous white to nearly white emulsion after shaking.

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

No data available.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for *Suidae*, inactivated viral and inactivated bacterial vaccines for pigs.
ATCvet code: QI09AL08

The product stimulates the development of active immunity against porcine circovirus type 2 and *Mycoplasma hyopneumoniae* in pigs.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitan oleate
Polysorbate 80
Ethyl alcohol
Glycerol
Sodium chloride
Water for injections

6.2 Major Incompatibilities

Do not mix with any other veterinary medicinal product, except Porcilis Lawsonia lyophilisate.

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: 8 hours.

6.4 Special precautions for storage

Store in a refrigerator (2 °C - 8 °C).
Do not freeze.
Protect from direct sunlight.

6.5 Nature and composition of immediate packaging

PET (polyethylene terephthalate) vials of 20, 50, 100, 200 or 500 ml, closed with nitrile rubber stoppers and sealed with aluminium caps.

Cardboard box with 1 vial of 20 ml.
Cardboard box with 1 vial of 50 ml.
Cardboard box with 1 vial of 100 ml.
Cardboard box with 1 vial of 200 ml.
Cardboard box with 1 vial of 500 ml.

Cardboard box with 10 vials of 20 ml.
Cardboard box with 10 vials of 50 ml.
Cardboard box with 10 vials of 100 ml.
Cardboard box with 10 vials of 200 ml.
Cardboard box with 10 vials of 500 ml.

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, UK

8. MARKETING AUTHORISATION NUMBER

Vm 01708/5056

9. DATE OF FIRST AUTHORISATION

07 November 2014

10. DATE OF REVISION OF THE TEXT

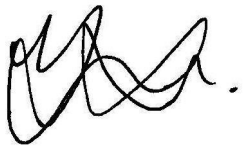
September 2023

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

POM-V Veterinary medicinal product subject to prescription.



Approved: 14 September 2023