ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis PCV M Hyo ID emulsion for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (0.2 ml) contains:

Active substances:

Porcine circovirus type 2 (PCV2), ORF2 capsid protein	≥ 751.4 AU[1]
Mycoplasma hyopneumoniae, strain J, inactivated	≥ 0.72 AU[1]

[1]Antigenic units as determined in the *in vitro* potency test

Adjuvants:

All-rac-α-tocopheryl acetate	15.88 mg
Squalane[2]	13.50 mg

[2] Synthetic Squalane

Excipients:

Qualitative composition of excipients and other constituents
Polysorbate 80
Silica, colloidal anhydrous[1]
Sodium dihydrogen phosphate dihydrate
Disodium phosphate dihydrate
Sodium chloride
Water for injections

[1] Silica fumed, nanosized

Homogenous white to nearly white emulsion after shaking.

3. CLINICAL INFORMATION

3.1 Target species

Pigs.

3.2 Indications for use for each target species

For the active immunisation of pigs:

- to reduce viremia, virus load in lungs and lymphoid tissues, and faecal virus shedding caused by porcine circovirus type 2 (PCV2) infection and severity of lung lesions caused by *Mycoplasma hyopneumoniae* infection and
- to reduce the loss of daily weight gain during the finishing period in face of infections with PCV2 and/or *M. hyopneumoniae*.

Onset of immunity:
PCV2: 2 weeks after vaccination,
M. hyopneumoniae: 4 weeks after vaccination.

Duration of immunity:
PCV2: 26 weeks after vaccination,
M. hyopneumoniae: 18 weeks after vaccination.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Use of the vaccine in boars has not been evaluated and is therefore not recommended.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
None.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Pigs:

Very common (>1 animal / 10 animals treated):	Elevated temperature[1]; Injection site swelling[2]; Injection site scabs[3]
Uncommon (1 to 10 animals / 1,000 animals treated)	Hypersensitivity reaction

[1] Mean increase of 1 °C, up to 1.8°C in individual piglets, and up to 2.6 °C in individual breeding pigs. The animals return to normal within 1 to 2 days after peak temperature.

[2] Hard non-painful with a mean diameter of up to 3 cm in piglets and 5 cm in breeding pigs. The size may increase up to 6 cm in individual piglets and up to 12 cm in individual breeding pigs. A biphasic pattern, consisting of an increase and decrease followed by another increase and decrease of the size may be observed. Disappears within approximately 8 weeks after vaccination.

[3] Scabs of round or elongated shape may be observed and can last at least until 9 weeks post vaccination.

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 the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy and lactation.

3.8 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 mixed and administered with Porcilis Lawsonia ID (see section 3.9 below) and/or administered on the same day but not mixed with Porcilis PRRS. The administration site of non-mixed

vaccines should be separated by approximately 3 cm. The product literature of Porcilis Lawsonia ID and/or Porcilis PRRS should be consulted before administration.

Adverse events are as described in 3.6, except for injection site swellings with a maximum diameter of up to 15 cm in individual breeding pigs. Injection site may show other signs of inflammation (pain, reddening, warmth and crusts).

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.

3.9 Administration routes and dosage

For intradermal use.

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

Intradermal administration in the neck of 0.2 ml per animal using a multi-dose needle-free injection device for intradermal application of liquids suitable to deliver a "jet-stream" volume of vaccine (0.2 ml ± 10 %) through the epidermal layers of the skin.

Safety and efficacy of Porcilis PCV M Hyo ID have been demonstrated using the device IDAL.

Vaccination scheme:
A single dose is given to pigs from 3 weeks of age onwards.

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

Porcilis Lawsonia ID lyophilisate	Porcilis PCV M Hyo ID
50 doses	10 ml
100 doses	20 ml
200 doses	40 ml

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

Dosage:
A single dose (0.2 ml) of Porcilis Lawsonia ID lyophilisate reconstituted in Porcilis PCV M Hyo ID is given intradermally in the neck.

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

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Not applicable.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI09AL08.

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

Revaccination with a single dose after 18 weeks induces an anamnestic serological immune response in female breeding pigs.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product except those mentioned in section 3.8.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 8 hours.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Glass vial (type I) or PET (polyethylene terephthalate) vial of 10 ml closed with a nitryl-based or chlorobutyl-based rubber stopper and sealed with an aluminium cap.

PET (polyethylene terephthalate) vials of 20 ml and 40 ml closed with a nitryl-based or chlorobutyl-based rubber stopper and sealed with an aluminium cap.

Pack sizes:
Cardboard box with 1 glass vial of 10 ml (50 doses/vial).
Cardboard box with 10 glass vials of 10 ml (50 doses/vial).
Cardboard box with 1 PET vial of 10 ml (50 doses/vial).
Cardboard box with 10 PET vials of 10 ml (50 doses/vial).
Cardboard box with 1 PET vial of 20 ml (100 doses/vial).
Cardboard box with 10 PET vials of 20 ml (100 doses/vial).
Cardboard box with 1 PET vial of 40 ml (200 doses/vial).
Cardboard box with 10 PET vials of 40 ml (200 doses/vial).

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/24/319/001-008

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 30/08/2024.

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis PCV M Hyo ID emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (0.2 ml) contains:

Porcine circovirus type 2 (PCV2) ORF2 capsid protein	≥ 751.4 AU
Mycoplasma hyopneumoniae, strain J, inactivated	≥ 0.72 AU

3. PACKAGE SIZE

10 ml (50 doses)
20 ml (100 doses)
40 ml (200 doses)
10 x 10 ml (10 x 50 doses)
10 x 20 ml (10 x 100 doses)
10 x 40 ml (10 x 200 doses)

4. TARGET SPECIES

Pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intradermal use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 8 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not freeze.
Protect from direct sunlight.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBERS

EU/2/24/319/001 (1 x 10 ml glass vial)
EU/2/24/319/002 (10 x 10 ml glass vials)
EU/2/24/319/003 (1x 10 ml PET vial)
EU/2/24/319/004 (10 x 10 ml PET vials)
EU/2/24/319/005 (1 x 20 ml PET vial)
EU/2/24/319/006 (10 x 20 ml PET vials)
EU/2/24/319/007 (1 x 40 ml PET vial)
EU/2/24/319/008 (10 x 40 ml PET vials)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass or PET vials of 10 ml PET vials of 20 or 40 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis PCV M Hyo ID

2. STATEMENT OF ACTIVE SUBSTANCES

PCV2 ORF2 capsid protein
M. hyopneumoniae inac.

10 ml (50 doses)
20 ml (100 doses)
40 ml (200 doses)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 8 hours.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Porcilis PCV M Hyo ID emulsion for injection for pigs

2. Composition

Each dose (0.2 ml) contains:

Active substances:

Porcine circovirus type 2 (PCV2), ORF2 capsid protein	≥ 751.4 AU[1]
Mycoplasma hyopneumoniae, strain J, inactivated	≥ 0.72 AU[1]

[1]Antigenic units as determined in the *in vitro* potency test

Adjuvants:

All-rac-α-tocopheryl acetate	15.88 mg
Squalane[2]	13.50 mg

[2] Synthetic Squalane

Homogenous white to nearly white emulsion after shaking.

3. Target species

Pigs.

4. Indications for use

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

Onset of immunity:
PCV2: 2 weeks after vaccination,
M. hyopneumoniae: 4 weeks after vaccination.

Duration of immunity:
PCV2: 26 weeks after vaccination,
M. hyopneumoniae: 18 weeks after vaccination.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Special precautions for safe use in the target species:
Use of the vaccine in boars has not been evaluated and is therefore not recommended.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
None.

Special precautions for the protection of the environment:
Not applicable.

Pregnancy and lactation:
Can be used during pregnancy and lactation.

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 mixed and administered with Porcilis Lawsonia ID and/or administered on the same day but not mixed with Porcilis PRRS. The administration site of non-mixed vaccines should be separated by approximately 3 cm. The product literature of Porcilis Lawsonia ID and/or Porcilis PRRS should be consulted before administration.

Adverse events are as described in the below section, except for injection site swellings with a maximum diameter of up to 15 cm may occur in individual breeding pigs. Injection site may show other signs of inflammation (pain, reddening, warmth and crust).

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.

Major incompatibilities:
Do not mix with any other veterinary medicinal product except those mentioned above.

7. Adverse events

Pigs:

Very common (>1 animal / 10 animals treated):	Elevated temperature[1]; Injection site swelling[2]; Injection site scabs[3]
Uncommon (1 to 10 animals / 1,000 animals treated):	Hypersensitivity reaction

[1] Mean increase of 1 °C, up to 1.8 °C in individual piglets, and up to 2.6 °C in individual breeding pigs. The animals return to normal within 1 to 2 days after peak temperature.

[2] Hard non-painful with a mean diameter of up to 3 cm in piglets and 5 cm in breeding pigs. The size may increase up to 6 cm in individual piglets and up to 12 cm in individual breeding pigs. A biphasic pattern, consisting of an increase and decrease followed by another increase and decrease of the size may be observed. Disappears within approximately 8 weeks after vaccination.

[3] Scabs of round or elongated shape may be observed and can last at least until 9 weeks post vaccination.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

For intradermal use.

Intradermal administration in the neck of 0.2 ml per animal using a multi-dose needle-free injection device for intradermal application of liquids suitable to deliver a "jet-stream" volume of vaccine (0.2 ml ± 10 %) through the epidermal layers of the skin.

Safety and efficacy of Porcilis PCV M Hyo ID have been demonstrated using the device IDAL.

Vaccination scheme:
A single dose is given to pigs from 3 weeks of age onwards.

Mixed use with Porcilis Lawsonia ID
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Porcilis Lawsonia ID lyophilisate	Porcilis PCV M Hyo ID
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For proper reconstitution and correct administration, use the following procedure:
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2. Add approximately 5-10 ml of Porcilis PCV M Hyo ID to the Porcilis Lawsonia ID lyophilisate and mix briefly.
3. Withdraw the reconstituted concentrate from the vial and transfer it back into the vial with the Porcilis PCV M Hyo ID. Shake briefly to mix.
4. Use the vaccine suspension within 6 hours of reconstitution. Any vaccine remaining at the end of this time should be discarded.

Dosage:
A single dose (0.2 ml) of Porcilis Lawsonia ID lyophilisate reconstituted in Porcilis PCV M Hyo ID is given intradermally in the neck.

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

9. Advice on correct administration

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

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 8 hours.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/24/319/001-008

Cardboard box with 1 glass vial of 10 ml (50 doses).
Cardboard box with 10 glass vials of 10 ml (10 x 50 doses).
Cardboard box with 1 PET vial of 10 ml (50 doses).
Cardboard box with 10 PET vials of 10 ml (10 x 50 doses).
Cardboard box with 1 PET vial of 20 ml (100 doses).
Cardboard box with 10 PET vials of 20 ml (10 x 100 doses).
Cardboard box with 1 PET vial of 40 ml (200 doses).
Cardboard box with 10 PET vials of 40 ml (10x 200 doses).
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

<{MM/YYYY}>

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:
Intervet International B.V., Wim de Körverstraat 35, 5831 AN Boxmeer, The Netherlands

België/Belgique/Belgien
Tél/Tel: + 32 (0)2 370 94 01

Република България
Тел: + 359 28193749

Česká republika
Tel: + 420 233 010 242

Danmark
Tlf: + 45 44 82 42 00

Deutschland
Tel: + 49 (0)8945614100

Eesti
Tel: + 37052196111

Ελλάδα
Τηλ: + 30 210 989 7452

España
Tel: + 34 923 19 03 45

France
Tél: + 33 (0)241228383

Hrvatska
Tel: + 385 1 6611339

Ireland
Tel: + 353 (0) 1 2970220

Ísland
Sími: + 354 535 7000

Italia
Tel: + 39 02 516861

Κύπρος
Τηλ: + 30 210 989 7452

Latvija
Tel: + 37052196111

Lietuva
Tel: + 37052196111

Luxembourg/Luxemburg
Tél/Tel: + 32 (0)2 370 94 01

Magyarország
Tel.: + 36 1 439 4597

Malta
Tel: + 39 02 516861

Nederland
Tel: + 32 (0)2 370 94 01

Norge
Tlf: + 47 55 54 37 35

Österreich
Tel: + 43 (1) 256 87 87

Polska
Tel.: + 48 22 18 32 200

Portugal
Tel: + 351 214 465 700

România
Tel: + 40 21 311 83 11

Slovenija
Tel: + 385 1 6611339

Slovenská republika
Tel: + 420 233 010 242

Suomi/Finland
Puh/Tel: + 358 10 2310 750

Sverige
Tel: + 46 (0)8 522 216 60

United Kingdom (Northern Ireland)
Tel: + 353 (0) 1 2970220

17. Other information

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

Revaccination with a single dose after 18 weeks induces an anamnestic serological immune response in female breeding pigs.