ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis PCV emulsion for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose contains:

Active substance:
Porcine circovirus type 2 ORF2 subunit antigen: ≥ 3720 AU*

* Antigenic Units as determined in the *in vitro* potency test (AlphaLISA)

Adjuvants:
Dl-α-tocopheryl acetate 25 mg
Light liquid paraffin 346 mg

Excipients:

Qualitative composition of excipients and other constituents
Polysorbate 80
Simethicone
Water for injections

Opalescent white, with brown resuspendable sediment.

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 the virus load in blood and lymphoid tissues and to reduce mortality and weight loss associated with PCV2 infection occurring during the fattening period.

Onset of immunity: 2 weeks
Duration of immunity: 22 weeks

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:
From the data provided, it can be concluded that a single dose regimen of vaccination breaks through up to medium levels and double dose regimen through medium to high levels of maternally derived antibodies in piglets.
No data are available on the use of the vaccine in breeding boars.

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.

3.6 Adverse events

Pigs:

Very common (>1 animal / 10 animals treated):	Injection site swelling[1], Elevated temperature[2].
Common (1 to 10 animals / 100 animals treated):	Hypersensitivity reaction[3].
Uncommon (1 to 10 animals / 1,000 animals treated):	Elevated temperature[4], Depression[5], Reduced food intake[5].
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactic-type reaction[6].

[1] In the form of a hard, warm and sometimes painful swelling (diameter up to 10 cm). These reactions resolve spontaneously over a period of approximately 14–21 days without any major consequence on the general health status of the animals.
[2] Normally not exceeding 1 °C, observed until 2 days after vaccination.
[3] Resulting in minor neurological symptoms such as tremors and/or excitation, which normally resolve within minutes without requiring treatment.
[4] In individual animals, an increase of rectal temperature of 2.5 °C lasting less than 24 hours.
[5] Up to 5 days, may result in transient impairment of growth rate in the immediate period after the administration of the vaccine.
[6] May be life-threatening. In the event of such reactions, treatment may be needed.

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:
Do not use during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

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 decided on a case by case basis.

3.9 Administration routes and dosage

Before using the vaccine, allow it to reach room temperature and shake well before use. Avoid multiple vial broaching. Use sterile syringes and needles. Avoid introduction of contamination. Avoid use of vaccination equipment with rubber parts.

Vaccination
Administer one dose of 2 ml by intramuscular injection in the neck, in the area behind the ear, according to the following schedule:

In the case of low to medium levels of maternally derived antibodies against PCV2 a single vaccination (2 ml) to pigs from an age of 3 weeks onwards is advised.

When it is expected that higher levels of maternally derived antibodies against PCV2 are present, the following schedule of two vaccinations is advised: the first injection (2 ml) can be given from an age of 3–5 days, the second injection (2 ml) 2–3 weeks later.

High levels of MDA may be expected when sows/gilts are vaccinated against PCV2 virus or when sows/gilts have recently been exposed to high levels of PCV2 virus. In such cases it is advised to perform PCV2 serology, using suitable diagnostics, to select the most appropriate vaccination schedule. In case of doubt, apply the two shot vaccination schedule.

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

Following the administration of a double dose of vaccine no side effects other than those described in section 3.6 have been observed.

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: QI09AA07.

Vaccine to stimulate active immunity against porcine circovirus type 2.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 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 light.

5.4 Nature and composition of immediate packaging

PET (polyethylene terephthalate) vials of 20, 50, 100, 200 or 500 ml are closed with a nitryl rubber stopper and a coded aluminium cap.

Pack sizes:
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.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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/2/08/091/001
EU/2/08/091/002
EU/2/08/091/003
EU/2/08/091/004
EU/2/08/091/005
EU/2/08/091/006
EU/2/08/091/007
EU/2/08/091/008

EU/2/08/091/009
EU/2/08/091/010

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 12/01/2009.

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

{MM/YYYY}

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 BOXES {20, 50, 100, 200 and 500 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis PCV emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose of 2 ml:
Porcine circovirus type 2 ORF2 subunit antigen: ≥ 3720 Antigenic Units.

3. PACKAGE SIZE

20 ml
50 ml
100 ml
200 ml
500 ml
10 x 20 ml
10 x 50 ml
10 x 100 ml
10 x 200 ml
10 x 500 ml

4. TARGET SPECIES

Pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular 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 light.

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/2/08/091/001	20 ml
EU/2/08/091/002	50 ml
EU/2/08/091/003	100 ml
EU/2/08/091/004	200 ml
EU/2/08/091/005	500 ml
EU/2/08/091/006	10 x 20 ml
EU/2/08/091/007	10 x 50 ml
EU/2/08/091/008	10 x 100 ml
EU/2/08/091/009	10 x 200 ml
EU/2/08/091/010	10 x 500 ml

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

PET VIALS {100, 200 and 500 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis PCV emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose of 2 ml:
PCV2 ORF2 subunit antigen: ≥ 3720 Antigenic Units.

100 ml
200 ml
500 ml

3. TARGET SPECIES

Pigs

4. ROUTES OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: zero days.

6. EXPIRY DATE

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

7. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not freeze. Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

PET VIAL {20 and 50 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis PCV

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Per dose of 2 ml:
PCV2 ORF2 subunit antigen: ≥ 3720 Antigenic Units.

20 ml
50 ml

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 emulsion for injection for pigs

2. Composition

Each 2 ml dose contains:

Active substance:
Porcine circovirus type 2 ORF2 subunit antigen: ≥ 3720 AU*
*Antigenic Units as determined in the *in vitro* potency test (AlphaLISA)

Adjuvants:
Dl-α-tocopheryl acetate 25 mg
Light liquid paraffin 346 mg

Opalescent white, with brown resuspendable sediment.

3. Target species

Pigs.

4. Indications for use

For the active immunisation of pigs to reduce the virus load in blood and lymphoid tissues and to reduce mortality and weight loss associated with PCV2 infection occurring during the fattening period.

Onset of immunity: 2 weeks
Duration of immunity: 22 weeks

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Special precautions for safe use in the target species:
From the data provided, it can be concluded that a single dose regimen of vaccination breaks through up to medium levels and double dose regimen through medium to high levels of maternally derived antibodies in piglets.
No data are available on the use of the vaccine in breeding boars.

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.

Pregnancy and lactation:
Do not use during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
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 decided on a case by case basis.

Overdose:
Following the administration of a double dose of vaccine no side effects other than those described under “Adverse events” have been observed.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Pigs:

Very common (>1 animal / 10 animals treated):	Injection site swelling[1], Elevated temperature[2].
Common (1 to 10 animals / 100 animals treated):	Hypersensitivity reaction[3].
Uncommon (1 to 10 animals / 1,000 animals treated):	Elevated temperature[4], Depression[5], Reduced food intake[5].
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactic-type reaction[6].

[1] In the form of a hard, warm and sometimes painful swelling (diameter up to 10 cm). These reactions resolve spontaneously over a period of approximately 14–21 days without any major consequence on the general health status of the animals.
[2] Normally not exceeding 1 °C, observed until 2 days after vaccination.
[3] Resulting in minor neurological symptoms such as tremors and/or excitation, which normally resolve within minutes without requiring treatment.
[4] In individual animals, an increase of rectal temperature of 2.5 °C lasting less than 24 hours.
[5] Up to 5 days, may result in transient impairment of growth rate in the immediate period after the administration of the vaccine.

[6] May be life-threatening. In the event of such reactions, treatment may be needed.

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

Administer one dose (2 ml), by intramuscular injection in the neck in the area behind the ear, according to the following schedule:

In the case of low to medium levels of maternally derived antibodies against PCV2 a single vaccination (2 ml) to pigs from an age of 3 weeks onwards is advised.

When it is expected that higher levels of maternally derived antibodies against PCV2 are present, the following schedule of two vaccinations is advised: the first injection (2 ml) can be given from an age of 3–5 days, the second injection (2 ml) 2–3 weeks later.

High levels of MDA may be expected when sows/gilts are vaccinated against PCV2 virus or when sows/gilts have recently been exposed to high levels of PCV2 virus. In such cases it is advised to perform PCV2 serology, using suitable diagnostics, to select the most appropriate vaccination schedule. In case of doubt, apply the two shot vaccination schedule.

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 multiple vial broaching.
Use sterile syringes and needles.
Avoid introduction of contamination.
Avoid use of vaccination equipment with rubber parts.

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 light.
Shelf-life after first opening the immediate packaging: 8 hours.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the vial. The expiry date refers to the last day of that month.

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/2/08/091/001–010

Pack sizes: cardboard boxes with either 1 or 10 vials of 20, 50, 100, 200 or 500 ml (10, 25, 50, 100 or 250 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

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

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

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