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 AND OTHER 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. INDICATION(S)

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

MSD Animal Health UK Ltd.

14. MARKETING AUTHORISATION NUMBERS

Vm 01708/5054

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

Accidental administration is dangerous.
Shake well before use.

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

Disposal: Read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V Veterinary medicinal product subject to prescription.

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 AND OTHER 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/yyyyy}
Once broached use within 8 hours.

7. SPECIAL STORAGE PRECAUTIONS

Keep vial in the outer carton.
Store in a refrigerator.
Do not freeze. Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.

9. BATCH NUMBER

Lot {number}

10. SPECIAL WARNING(S), IF NECESSARY

Accidental administration is dangerous.
Shake well before use.

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

Disposal: Read package leaflet.

14. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.

POM-V Veterinary medicinal product subject to prescription.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vials {20 and 50 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis PCV

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

Per 2 ml dose:
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.

5. ROUTE(S) OF ADMINISTRATION

IM use.

6. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE 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 WARNING(S)

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.

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:
E-mail: adverse.events@vmd.gov.uk
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 the last day of that month.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 01708/5054

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. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder and contact details to report suspected adverse reactions:
MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
MK7 7AJ, UK
Tel.: +44 (0)1908 685685

Manufacturer responsible for batch release:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

17. OTHER INFORMATION

POM-V Veterinary medicinal product subject to prescription.