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 ID emulsion for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Per 0.2 ml:
PCV2 ORF2 subunit antigen ≥ 1436 AU

3. PACKAGE SIZE

10 ml
20 ml
10 x 10 ml
10 x 20 ml

4. TARGET SPECIES

Pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intradermal use.

7. WITHDRAWAL PERIODS

Withdrawal period: zero days.

8. EXPIRY DATE

EXP {month/year}
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.
To be supplied only on veterinary prescription.

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 AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
MK7 7AJ

14. MARKETING AUTHORISATION NUMBER

Vm 01708/5055

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIALS OF 10 AND 20 ML

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis PCV ID

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

PCV2 ORF2 subunit antigen

10 ml
20 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

EXP{mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Porcilis PCV ID emulsion for injection for pigs

1. Name of the veterinary medicinal product

Porcilis PCV ID emulsion for injection for pigs

2. Composition

Each dose of 0.2 ml contains:

Active substance:

Porcine circovirus type 2 ORF2 subunit antigen	≥ 1436 AU[1]

Adjuvants:

dl-α-tocopheryl acetate	0.6 mg
Light liquid paraffin	8.3 mg

[1]Antigenic units as determined in the *in vitro* antigenic mass assay.

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

3. Target species

Pigs

4. Indications for use

For the active immunisation of pigs to reduce viraemia, virus load in lungs and lymphoid tissues and virus shedding caused by PCV2 infection. To reduce loss of daily weight gain and mortality associated with PCV2 infection.

Onset of immunity: 2 weeks after vaccination.
Duration of immunity: 23 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.

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 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:
Can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction
Safety and efficacy data are available in pigs from 3 weeks of age onwards which demonstrate that this vaccine can be administered mixed with Porcilis Lawsonia ID (see section 8 below) and/or non-mixed with Porcilis M Hyo ID ONCE and/or non-mixed with Porcilis PRRS (intradermal route). The administration site of non-mixed vaccines should be separated by at least 3 cm.
The product literature of Porcilis Lawsonia ID, Porcilis M Hyo ID ONCE and Porcilis PRRS should be consulted before administration.
Adverse events are as described in section 7, except for injection site swelling where a maximum size of up to 7 cm may occur in individual pigs. Injection site swelling may last up to 7 weeks and are very commonly accompanied by redness and crusts. If the crust is rubbed off, some small skin damage may be commonly observed. Elevated temperature on the day of vaccination (mean 0.3 °C, in individual pigs up to 2 °C) is common. The animal’s temperature returns to normal within 1 – 2 days after the peak temperature is observed. Lying down and malaise can be uncommonly observed in vaccinated pigs.
Indications are as described in section 4, except for a duration of immunity of 26 weeks after vaccination is demonstrated.

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 made on a case by case basis.

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

7. ADVERSE REACTIONS

Pigs:

Very common (>1 animal / 10 animals treated):	Injection site swelling*

* mostly consisting of hard non-painful swellings of up to 2 cm diameter. A biphasic pattern of the injection site swelling, consisting of an increase and decrease followed by another increase and decrease of the size, is commonly observed. In individual pigs the size may increase to 6.5 cm and redness and/or scabs may be observed. The injection site swellings disappear completely within approximately 7 weeks after 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 local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. Dosage for each species, route(s) and method of administration

For intradermal use.
Intradermal administration of 0.2 ml per animal, preferably at the sides of the neck, along the muscles of the back or in the hind leg (all pigs) or perianal area (in pigs for reproduction) 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 ID have been demonstrated using the device IDAL.

Vaccination scheme:
Vaccinate once from an age of 3 weeks onwards and re-vaccination at 23 weeks interval is recommended.

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

Porcilis Lawsonia ID lyophilisate	Porcilis PCV ID
50 doses	10 ml
100 doses	20 ml

For proper reconstitution and correct administration, use the following procedure:
1. Allow Porcilis PCV ID to reach room temperature and shake well before use.
2. Add approximately 5-10 ml of Porcilis PCV 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 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 mixed with Porcilis PCV ID is given intradermally in the neck.

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

Avoid introduction of a contamination by multiple broaching.

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 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.
Shelf life after first opening the container: 8 hours.

12. Special precautions for disposal

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 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.

Detailed information on this veterinary medicinal product is available in the Union Product Database

14. Marketing authorisation numbers and pack sizes

Vm 01708/5055

Cardboard box with 1 glass vial of 10 ml.
Cardboard box with 10 glass vials of 10 ml.
Cardboard box with 1 PET vial of 20 ml.
Cardboard box with 10 PET vials of 20 ml.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this product is available in the Union Product Database.

16 Contact details

Marketing authorisation holder:
MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release: [1]
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ, United Kingdom

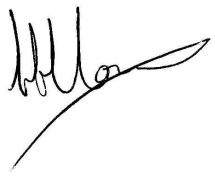
[1]The printed package leaflet will state the name and address of the manufacturer responsible for the release of the concerned batch only.

Contact details to report suspected adverse reactions:

UK(GB)	UK(NI)
MSD Animal Health UK Ltd.	Intervet Ireland Ltd.
Walton Manor, Walton	Magna Drive
Milton Keynes	Magna Business Park
Buckinghamshire	Citywest Road
MK7 7AJ, UK	Dublin 24, Ireland
Tel.: +44 (0)1908 685685	Tel.: +353 (0)1 2970220

17. Other information

The vaccine stimulates active immunity against porcine circovirus type 2.



Approved 17 October 2023