

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis PCV ID emulsion for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 0.2 ml contains:

Active substance:

Porcine circovirus type 2 ORF2 subunit antigen	≥ 1436 AU ¹
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Adjuvants:

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

¹ Antigenic units as determined in the *in vitro* potency test (antigenic mass assay).

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.

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 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.

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

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 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.

4.6 Adverse reactions (frequency and seriousness)

Transient local reactions mostly consisting of hard non-painful swellings of up to 2 cm diameter were very commonly observed in laboratory studies and field trials. A biphasic pattern of the local reactions, 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 local reactions disappear completely within approximately 7 weeks after vaccination.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine can be given with Porcilis M Hyo ID ONCE on the same day from 3 weeks of age, either at different sites (e.g. alternate sides of the neck), or at the same site providing that intradermal administration of each vaccine is separated by at least 3 cm.

The product literature of Porcilis M Hyo ID ONCE should be consulted. In case both vaccines are used on the same day the size of the local reactions may increase up to 6 cm in individual pigs, may last 7 weeks and are very commonly accompanied by redness and crusts. In the event that the crust is rubbed off, some small skin damage may be commonly observed. Moreover, a transient increase in body temperature on the day of vaccination of about 0.2 °C is common. In individual pigs this temperature may increase up to 2 °C. The animal's temperature returns to normal within 1-2 days after the peak temperature is observed.

Safety and efficacy data are available in pigs from 3 weeks of age onwards which demonstrate that this vaccine can be mixed with Porcilis Lawsonia ID (see section 4.9 below). The product literature of Porcilis Lawsonia ID should be consulted before administration. Adverse reactions are as described in section 4.6, except for local injection site reactions where a maximum size of up to 7 cm may occur in individual pigs.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except for 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 Amounts to be administered and administration route

For intradermal use.

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

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 ID 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.

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 vaccines for pigs.
ATCvet code: QI09AA07

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polysorbate 80
Simethicone
Sodium chloride
Potassium chloride
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
dl- α -tocopheryl acetate
Light liquid paraffin
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 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.

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

Glass vial (type I) of 10 ml closed with a nitril-based rubber stopper and sealed with an aluminium cap.

PET (polyethylene terephthalate) vial of 20 ml closed with a nitril-based rubber stopper and sealed with an aluminium cap.

Pack size:

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.

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

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxtmeer
The Netherlands

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/015/187/001-004

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28/08/2015
Date of last renewal: 27/05/2020

10. DATE OF REVISION OF THE TEXT

{MM/YYYY}

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (<http://www.ema.europa.eu/>).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.