# SUMMARY OF PRODUCT CHARACTERISTICS

## 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]

**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).

**Excipients:**
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: 26 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 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.

Other precautions:
Not applicable.

## 4.6 Adverse reactions (frequency and seriousness)

Pigs:

| | |
|---|---|
| Very common<br>(>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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See also the last section of the package leaflet for respective contact details.

## 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 in pigs from 3 weeks of age onwards which demonstrate that this vaccine can be administered mixed with Porcilis Lawsonia ID (see section 4.9 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 4.6, except for local injection site reactions where a maximum size of up to 7 cm may occur in individual pigs. Injection site reactions 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 body 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.

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 Amount(s) 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.

<u>Vaccination scheme:</u>
Vaccinate once from an age of 3 weeks onwards and re-vaccination at 26 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 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
Water for injections

## 6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product except those mentioned in section 4.8.

## 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 nitryl-based rubber stopper and sealed with an aluminium cap.

PET (polyethylene terephthalate) vial of 20 ml closed with a nitryl-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

Medicines should not be disposed of via wastewater.
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

MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
MK7 7AJ

## 8. MARKETING AUTHORISATION NUMBER

Vm 01708/5055

## 9. DATE OF FIRST AUTHORISATION

28 August 2015

## 10. DATE OF REVISION OF THE TEXT

June 2024

## 11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

*Gavin Hall*

Approved: 27 June 2024