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:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection.
Opalescent white, with brown resuspendable sediment.

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 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.

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:
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.

Other precautions:
Not applicable.

4.6 Adverse reactions (frequency and seriousness)

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 contact details.

4.7 Use during pregnancy, lactation or lay

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

4.8 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.

4.9 Amounts to be administered and administration route

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.

4.10 Overdose (symptoms, emergency procedures, antidotes),if necessary

Following the administration of a double dose of vaccine no side effects other than those described in section 4.6 have been observed.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated porcine circovirus vaccine.
ATCvet code: QI09AA07.

Vaccine to stimulate active immunity against porcine circovirus type 2.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polysorbate 80
Simethicone
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: 3 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 light.

6.5 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.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products 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
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 01708/5054

9. DATE OF FIRST AUTHORISATION

12 January 2009

10. DATE OF REVISION OF THE TEXT

March 2024

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.



Approved 11 May 2024