

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CircoMax emulsion for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

2 ml contains:

Active substances:

Inactivated recombinant chimeric porcine circovirus type 1 containing the porcine circovirus type 2a open reading frame 2 (ORF2) protein	1.5 – 4.9 RP*
Inactivated recombinant chimeric porcine circovirus type 1 containing the porcine circovirus type 2b ORF2 protein	1.5 – 5.9 RP*

Adjuvant:

MetaStim containing:

Squalane	0.4% (v/v)
Poloxamer 401	0.2% (v/v)
Polysorbate 80	0.032% (v/v)

* Relative potency unit determined by ELISA antigen quantification (*in vitro* potency test) compared to a reference vaccine.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection

White homogenous emulsion.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs (for fattening).

4.2 Indications for use, specifying the target species

Active immunisation of pigs against porcine circovirus type 2 to reduce viral load in blood and lymphoid tissues, fecal shedding and the lesions in lymphoid tissues associated with PCV2 infection. Protection was demonstrated against porcine circovirus types 2a, 2b and 2d.

Onset of immunity (both vaccination schedules): 3 weeks after (the last) vaccination.
Duration of immunity (both vaccination schedules): 23 weeks after (the last) 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

No information is available on the safety of this vaccine in breeding boars. Do not use in breeding boars.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

None.

4.6 Adverse reactions (frequency and seriousness)

A transient increase in body temperature, not exceeding 2.1°C, is very common after vaccination and resolves spontaneously within 24 hours without treatment. In a laboratory study, a post-mortem examination of the injection site, performed 2 weeks after the administration of a repeated single dose of the vaccine, very commonly revealed a mild lymphocytic-granulomatous inflammatory response, as evidenced by the absence of tissue necrosis and fibrosis. Local tissue reactions in the form of swelling at the injection site, below 2 cm in diameter, are common and may last for up to 10 days. Erythema may be uncommonly observed during the first 24 hours after vaccination. Hypersensitivity reactions, vomiting, incoordination, lethargy, and laboured breathing were uncommonly observed in field studies. The animals mostly recover within 24 hours.

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

The safety of the veterinary medicinal product has not been established during pregnancy or 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 made on a case by case basis.

4.9 Amounts to be administered and administration route

Vaccinate pigs by the intramuscular route in the neck behind the ear.

Single dose vaccination schedule

A single dose of 2 ml in pigs from 3 weeks of age.

Split dose vaccination schedule

Two injections each of 1 ml in pigs from 3 days of age with an interval of approximately 3 weeks.

Choice of dosing regimen, including age of vaccination should take into account farm circumstances. In situations where the level of maternally-derived antibodies against PCV2 is expected to be moderately high or very high, it is recommended to use the split dose vaccination schedule or to delay the age of vaccination.

Shake well before administration and intermittently during the process of vaccination.

The use of a multi-dosing syringe is recommended. Use vaccination devices according to the manufacturer's instructions.

The vaccine is to be administered aseptically.

During storage, a slight black deposit may appear and the emulsion may separate into two distinct phases. Upon shaking, the black deposit disappears and the emulsion becomes homogenous again.

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

In supportive overdose studies, lethargy and polypnoea have been observed. Transient mild injection site swellings can occur for up to 1 day. Transient fever (maximum 41.1°C) may occur for up to 12 hours.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: immunologicals for Suidae, inactivated viral vaccines for pigs.
ATCvet code: QI09AA07.

The vaccine contains an inactivated recombinant chimeric porcine circovirus type 1 expressing the porcine circovirus type 2a ORF2 protein and an inactivated recombinant chimeric porcine circovirus type 1 expressing the porcine circovirus type 2b ORF2 protein. The vaccine stimulates active immunity against multiple PCV2 genotypes in pigs.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Squalane
Poloxamer 401
Polysorbate 80
Monobasic potassium phosphate anhydrous
Sodium chloride
Potassium chloride
Disodium phosphate anhydrous
Sodium phosphate dibasic heptahydrate
Disodium tetraborate decahydrate
EDTA tetrasodium
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 package for sale: 18 months.
Shelf life after first opening the immediate packaging: use immediately.

6.4 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).

Do not freeze.

Protect from light.

A slight black deposit may appear and the emulsion may separate into two distinct phases during storage. Upon shaking, the black deposit disappears and the emulsion becomes homogenous again.

6.5 Nature and composition of immediate packaging

High density polyethylene vials of 50 ml, of 100 ml and of 250 ml, with a chlorobutyl elastomer closure and sealed with an aluminium cap.

Cardboard box of 1 vial of 50 ml, 100 ml or 250 ml.

Cardboard box of 10 vials of 50 ml or 100 ml.

Cardboard box of 4 vials of 250 ml.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste material derived from the use of such products, if appropriate

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with the local requirements.

7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

8. MARKETING AUTHORISATION NUMBER

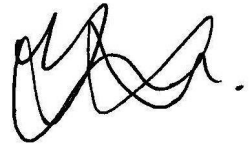
Vm 42058/5003

9. DATE OF FIRST AUTHORISATION

03 March 2022

10. DATE OF REVISION OF THE TEXT

March 2022

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved : 03 March 2022