SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CircoMax Myco emulsion for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose 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*
Inactivated Mycoplasma hyopneumoniae, strain P-5722-3	1.5 – 4.7 RP*

Adjuvant:

MetaStim containing:

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

Excipients:

Thiomersal	0.2 mg

*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.

Active immunisation of pigs against *Mycoplasma hyopneumoniae* to reduce the lung lesions associated with *Mycoplasma hyopneumoniae* infection.

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

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

In addition, vaccination has been shown to reduce body weight gain losses under field conditions.

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.

The use of a needle free device for intramuscular injection is not an appropriate method for delivery of the vaccine to 3-day old piglets.

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

None.

Special precautions for the protection of the environment:

Not applicable.

Other precautions

None.

4.6 Adverse reactions (frequency and seriousness)

Pigs for fattening:

Very common (>1 animal / 10 animals treated):	Elevated temperature (< 2.1 °C, resolving within 24 hours) Injection site swelling (between 2-5 cm in diameter, for 7 to 10 days)[a]
Uncommon (1 to 10 animals / 1,000 animals treated):	Erythema (in first 24 hours) Hypersensitivity reactions: vomiting, incoordination, lethargy, and laboured breathing (most recover within 24 hours)

[a] 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.

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

Pregnancy and lactation:

Not applicable.

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 Amount(s) 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 or a needle-free device for intramuscular injections is recommended. In each case, use vaccination devices according to the manufacturer's instructions. For needle-free administration use a needle-free device appropriate to deliver intramuscular injections of 2 ml dose in pigs from 3 weeks of age. The use of a needle free device for intramuscular injection is not an appropriate method for delivery of the vaccine to 3-day old piglets. Follow manufacturer's instructions specific to the pressure required to administer the required dose volume, and specific to handling and cleaning processes. Follow any restriction imposed by the device manufacturer specific to animal age or body weight limits.

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 41.1ºC) may occur for up to 12 hours.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Suidae, inactivated viral and inactivated bacterial vaccines for pigs

ATCvet Code: QI09AL08

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 also contains protective antigens from

inactivated Mycoplasma hyopneumoniae. The vaccine stimulates active immunity against multiple PCV2 genotypes and Mycoplasma hyopneumoniae in pigs.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Thiomersal

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 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

Zoetis UK Limited

1st Floor, Birchwood Building

Springfield Drive

Leatherhead

Surrey

KT22 7LP

8. MARKETING AUTHORISATION NUMBER

Vm 42058/5013

9. DATE OF FIRST AUTHORISATION

09 December 2020

10. DATE OF REVISION OF THE TEXT

February 2025

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

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: 21 February 2025