PARTICULARS TO APPEAR ON THE OUTER PACKAGE Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CircoMax Myco Emulsion for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

2 ml contains:

Inactivated recombinant chimeric porcine circovirus type 1 containing the porcine circovirus type 2a 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 antigens, strain P-5722-3 (1.5 – 4.7 RP)

3. PACKAGE SIZE

50 ml

100 ml

250 ml

10 x 50 ml

10 x 100 ml

4 x 250 ml

4. TARGET SPECIES

Pigs (for fattening)

5. INDICATION

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period(s): Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.

Do not freeze. Protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 42058/5013

15. BATCH NUMBER

Lot: {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V (‘Veterinary medicinal product subject to prescription’)

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - HDPE Vials (250ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CircoMax Myco Emulsion for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

2 ml contains:

Inactivated recombinant chimeric PCV type 1 containing PCV type 2a ORF2 protein (1.5 – 4.9 RP)

Inactivated recombinant chimeric PCV type 1 containing PCV type 2b ORF2 protein (1.5 – 5.9 RP)

Inactivated Mycoplasma hyopneumoniae, strain P-5722-3 (1.5 – 4.7 RP)

3. TARGET SPECIES

Pigs (for fattening)

4. ROUTES OF ADMINISTRATION

IM

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period(s): Zero Days

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use immediately

7. SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer carton.

Store and transport refrigerated.

Do not freeze. Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited

9. BATCH NUMBER

Lot: {number}

10. SPECIAL WARNING(S), IF NECESSARY

11. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet

12. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.

POM-V (‘Veterinary medicinal product subject to prescription’)

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS - HDPE vials (50 ml or 100 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CircoMax Myco

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Inactivated recombinant chimeric PCV type 1 containing the PCV type 2a ORF2 protein (1.5 – 4.9 RP) and the PCV type 2b ORF2 protein (1.5 – 5.9 RP).

Inactivated Mycoplasma hyopneumoniae, strain P-5722-3 (1.5 – 4.7 RP).

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {month/year}

Once broached use immediately.

5. ROUTE(S) OF ADMINISTRATION

IM

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CircoMax Myco Emulsion for injection for pigs

2. 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)

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

White homogenous emulsion.

3. TARGET SPECIES

Pigs (for fattening).

4. INDICATIONS FOR USE

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.

5. CONTRAINDICATIONS

None.

6. SPECIAL WARNING(S)

Special warnings:

Vaccinate healthy animals only.

Special precautions for safe use in target species:

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.

Pregnancy and lactation:

Not applicable.

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.

Overdose:

In supportive overdose studies, lethargy and polypnea 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.

Special restrictions for use and special conditions for use:

Any person intending to manufacture, import, possess, sell, supply and use this veterinary medicinal product must first consult the relevant competent authority on the current vaccination policies, as these activities may be prohibited in a country on the whole or part of its territory pursuant to national legislation.

Major incompatibilities:

Do not mix with any other veterinary medicinal product.

7. ADVERSE EVENTS

Pigs for fattening:

Very common (>1 animal / 10 animals treated):	Elevated temperature (< 2.1 °C, resolving within 24 hours) Injection site swelling (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 animals recover within 24 hours)

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Intramuscular use, 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.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIODS

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Do not freeze.

Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the vial after Exp.

Shelf life after first opening the immediate packaging: use immediately.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 42058/5013

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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder:

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

Manufacturer responsible for batch release:

Zoetis Belgium
Rue Laid Burniat 1
1348 Louvain-La-Neuve
Belgium

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP
UK
Tel: +44 (0) 345 300 8034

17. OTHER INFORMATION

POM-V ('Veterinary medicinal product subject to prescription')

For animal treatment only.

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.

Gavin Hall

Approved 21 February 2025