product subject to prescription.

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(S)

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
Keep the vial in the outer carton.
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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER
GB only:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

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 To be supplied only on veterinary 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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

9. BATCH NUMBER
Lot: {number}

10. PACKAGE SIZE
250 ml

11. INDICATION(S)

12. SPECIAL WARNING(S), IF NECESSARY

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

Disposal: Read package leaflet

14. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.

POM-V To be supplied only on veterinary prescription

15. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/5013

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. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

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. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 ml
100 ml

6. ROUTE(S) OF ADMINISTRATION

IM

7. WITHDRAWAL PERIOD

Withdrawal period(s): Zero days.

8. 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)
Excipients:	
Thiomersal	0.2 mg

*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.

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 Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State 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)
Common (1 to 10 animals / 100 animals treated):	Injection site swelling (< 2 cm in diameter; for up to 10 days)
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, ROUTE(S) 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 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.

10. WITHDRAWAL PERIOD(S)

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

GB only: Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirement.

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. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

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

16. CONTACT DETAILS

Marketing authorisation holder and manufacturer responsible for batch release:

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

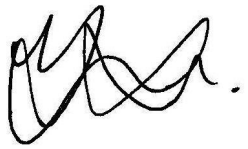
Local representatives and contact details to report suspected adverse reactions:

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

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

17. OTHER INFORMATION

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.



Approved : 03 May 2023