ANNEX II

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substance(s)

Zoetis WHC 2 LLC
2000 Rockford Road,
Charles City IA 50616
USA

Name and address of the manufacturer responsible for batch release

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

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

The active substances being principles of biological origin intended to produce active immunity are not within the scope of Regulation (EC) No 470/2009.

The excipients listed in section 6.1 of the SPC are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CircoMax Emulsion for injection for pigs (for fattening)

2. STATEMENT OF ACTIVE 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)

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

50 ml
100 ml
250 ml

10 x 50 ml
10 x 100 ml
4 x 250 ml

5. TARGET SPECIES

Pigs (for fattening)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP
Once broached use immediately.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze. Protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

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

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 42058/5003

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

HDPE vials (250 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CircoMax Emulsion for injection for pigs (for fattening)

2. STATEMENT OF ACTIVE 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)

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

250 ml

5. TARGET SPECIES

Pigs (for fattening)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

IM
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP
Once broached use immediately.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze. Protect from light

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 42058/5003

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

HDPE vials (50 ml or 100 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CircoMax Emulsion for injection for pigs

2. QUANTITY 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).

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

50 ml
100 ml

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP
Once broached use immediately.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
CircoMax Emulsion for injection for pigs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorization holder and manufacturer responsible for batch release:

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

CircoMax emulsion for injection for pigs

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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.

White homogenous emulsion.

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

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).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Pigs (for fattening).

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.
Once broached use immediately.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.

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.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy or lactation. Do not use during pregnancy and lactation.

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 (symptoms, emergency procedures, antidotes):
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.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

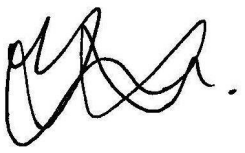
Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

15. 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 stimulates active immunity against multiple PCV2 genotypes in pigs.

Cardboard box of 1 vial (HDPE) of 50 ml, 100 ml or 250 ml.
Cardboard box of 10 vials (HDPE) of 50 ml or 100 ml.
Cardboard box of 4 vials (HDPE) of 250 ml.

Not all pack sizes may be marketed.



Approved : 03 March 2022