ANNEX I

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)

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

Excipients:

Qualitative composition of excipients and other constituents
Monobasic potassium phosphate anhydrous
Sodium chloride
Potassium chloride
Disodium phosphate anhydrous
Sodium phosphate dibasic heptahydrate
Disodium tetraborate decahydrate
EDTA tetrasodium
Water for injections

White homogenous emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (for fattening).

3.2 Indications for use for each 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.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the 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:
Not applicable.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

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 animals 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 the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Not applicable.

3.8 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.

3.9 Administration routes and dosage

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. 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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 ºC) may occur for up to 12 hours.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

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.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf life after first opening the immediate packaging: use immediately.

5.3 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.

5.4 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.

5.5 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 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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/20/264/001 - 006

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 09/12/2020.

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None.

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 Myco Emulsion for injection

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)
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. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: 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 Belgium

14. MARKETING AUTHORISATION NUMBERS

EU/2/20/264/001 (50 ml)
EU/2/20/264/002 (100 ml)
EU/2/20/264/003 (250 ml)
EU/2/20/264/004 (10 x 50 ml)
EU/2/20/264/005 (10 x 100 ml)
EU/2/20/264/006 (4 x 250 ml)

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

HDPE VIALS (250 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CircoMax Myco Emulsion for injection

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).
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: Zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use immediately.

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium

9. BATCH NUMBER

Lot {number}

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 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. {mm/yyyy}
Once broached use immediately.

B. PACKAGE LEAFLET

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 warnings

Special warnings:
Vaccinate healthy animals only.

Special precautions for safe use in the 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 polypnoea have been observed. Transient mild injection site swellings can occur for up to 1 day. Transient fever (maximum 41.1 ºC) 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) Injection site swelling (between 2-5 cm in diameter, for 7 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 marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

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.. 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 container: 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

EU/2/20/264/001 - 006.

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.

15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorization holder and 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 listed below.

België/Belgique/Belgien
Zoetis Belgium
Mercuriusstraat 20
BE-1930 Zaventem
Tél/Tel: +32 (0) 800 99 189

Република България
Zoetis Belgium
Rue Laid Burniat 1
1348 Louvain-La-Neuve
Белгия
Тел: +359 888 51 30 30

Česká republika
Zoetis Česká republika, s.r.o.
náměstí 14. října 642/17
CZ 150 00 Praha
Tel: +420 257 101 111

Lietuva
Zoetis Belgium
Mercuriusstraat 20
1930 Zaventem
Belgija
Tel: +370 610 05088

Luxembourg/Luxemburg
Zoetis Belgium
Mercuriusstraat 20
1930 Zaventem
Belsch
Tél/Tel: +32 (2) 746 80 11

Magyarország
Zoetis Hungary Kft.
Csörsz u. 41.
HU-1124 Budapest
Tel.: +36 1 224 5200

Danmark
Zoetis Animal Health ApS
Øster Alle 48
DK-2100 København
Tlf: +45 70 20 73 05
adr.scandinavia@zoetis.com

Deutschland
Zoetis Deutschland GmbH
Schellingstr. 1
DE-10785 Berlin
Tel: +49 30 2020 0049
tierarzneimittelsicherheit@zoetis.com

Eesti
Zoetis Belgium
Mercuriusstraat 20
1930 Zaventem
Belgia
Tel: +370 610 05088

Κύπρος
Zoetis Hellas S.A.
Φραγκοκκλησιάς 7, Μαρούσι
15125, Αττική
Ελλάδα
Τηλ: +30 210 6791900

España
Zoetis Spain, S.L.
Parque Empresarial Vía Norte Edificio nº1,
c/ Quintanavides nº13
ES-28050 Madrid
Tel: +34 91 4191900

France
Zoetis France
10 rue Raymond David
FR-92240 Malakoff
Tél: +33 (0) 800 73 00 65

Hrvatska
Zoetis B.V.
Podružnica Zagreb za promidžbu
Petra Hektorovića 2
HR-10000 Zagreb
Tel: +385 1 6441 462

Malta
Agrimed Limited
Mdina Road, Zebbug ZBG 9016,
MT
Tel: +356 21 465 797

Nederland
Zoetis B.V.
Rivium Westlaan 74
NL-2909 LD Capelle aan den IJssel
Tel: +31 (0)10 714 0900

Norge
Zoetis Animal Health ApS
Øster Alle 48
DK-2100 København
Danmark
Tlf: +47 23 29 86 80
adr.scandinavia@zoetis.com

Österreich
Zoetis Österreich GmbH
Floridsdorfer Hauptstr. 1
AT-1210 Wien
Tel: +43 (0)1 2701100 100

Polska
Zoetis Polska Sp. z o.o.
ul. Postępu 17B
PL - 02-676 Warszawa
Tel.: +48 22 2234800

Portugal
Zoetis Portugal Lda.
Lagoas Park, Edifício 10
PT-2740-271 Porto Salvo
Tel: +351 21 042 72 00

România
Zoetis România S.R.L.
Expo Business Park, 54A Aviator Popișteanu,
Clădirea 2, Etaj 1-3, Sector 1,București, 012095
- RO
Tel: +40785019479

Ireland
Zoetis Belgium S.A. (Irish Branch)
2nd Floor, Building 10, Cherrywood Business Park, Loughlinstown,
Co. Dublin,
IE – Dublin D18 T3Y1
Tel: +353 (0) 1 256 9800

Ísland
Zoetis Animal Health ApS
Øster Alle 48
DK-2100 København
Danmörku
Sími: +45 70 20 73 05

Italia
Zoetis Italia S.r.l.
Via Andrea Doria 41M,
IT-00192 Roma
Tel: +39 06 3366 8111

Ελλάδα
Zoetis Hellas S.A.
Φραγκοκκλησιάς 7, Μαρούσι
EL-15125 Αττική
Τηλ: +30 210 6791900

Latvija
Zoetis Belgium
Mercuriusstraat 20
1930 Zaventem
Belgija
Tel: +370 610 05088

Slovenija
Zoetis B.V.
Podružnica Zagreb za promidžbu
Petra Hektorovića 2,
10000 Zagreb,
Hrvaška
Tel: +385 1 6441 462

Slovenská republika
Zoetis Česká republika, s.r.o.
náměstí 14. října 642/17
150 00 Praha
Česká republika
Tel: +420 257 101 111

Suomi/Finland
Zoetis Finland Oy
Bulevardi 21 / SPACES
FI-00180 Helsinki/Helsingfors
Suomi/Finland
Puh/Tel: +358 10 336 7000
laaketurva@zoetis.com

Sverige
Zoetis Animal Health ApS
Øster Alle 48
DK-2100 Köpenhamn
Danmark
Tel: +46 (0) 76 760 0677
adr.scandinavia@zoetis.com

United Kingdom (Northern Ireland)
Zoetis Belgium S.A. (Irish Branch)
2nd Floor, Building 10
Cherrywood Business Park
Loughlinstown
Co. Dublin
IE – Dublin D18 T3Y1
Tel: +353 (0) 1 256 9800

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.