ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn Circo+MH RTU 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 2 ORF2 protein	2.3 – 12.4 RP*
Inactivated *Mycoplasma hyopneumoniae,* strain P-5722-3	1.5 – 3.8 RP*

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

Adjuvant:

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

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Thiomersal	0.2 mg
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.
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.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (for fattening).

3.2 Indications for use for each target species

For active immunisation of pigs from 3 weeks of age against porcine circovirus type 2 (PCV2) to

reduce viral load in blood and lymphoid tissues and faecal shedding caused by infection with PCV2.
For active immunization of pigs from the age of 3 weeks against *Mycoplasma hyopneumoniae* to reduce lung lesions caused by infection with *M. hyopneumoniae*.

Onset of immunity: 3 weeks.
Duration of immunity: 23 weeks.

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:
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

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[1] Injection site inflammation[2], Injection site pain[3], injection site reddening[3], injection site swelling[3]
Uncommon (1 to 10 animals / 1,000 animals treated):	Hypersensitivity reactions (e.g. depression, diarrhoea or vomiting)[4]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylaxis[5]

[1]Transient; observed during the first 24 hours after vaccination. On average 1° C but may exceed 2° C in individual pigs. This resolves spontaneously within 48 hours without treatment.
[2] Post-mortem examination of the injection site, performed 4 weeks after the administration of a repeated single dose of the vaccine very commonly revealed a mild lymphocytic-granulomatous inflammatory response.
[3]The area of local tissue reactions is in general below 2 cm in diameter and may last up to 2 days.
[4]Normally resolve without treatment.
[5]In case of such reactions, appropriate treatment is recommended.

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

The safety of the veterinary medicinal product has not been established during pregnancy or lactation.

Pregnancy and lactation:
Do not use during pregnancy and lactation.

Fertility:
No information is available on the safety of this vaccine in breeding boars. Do not use in breeding boars.

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

Intramuscular use.
Administer one dose of 2 ml to pigs in the neck behind the ear.

Vaccination schedule:
One injection from 3 weeks of age.

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.

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

A transient increase in body temperature (on average 0.8 °C) was observed 4 hours after administration of a 2-fold overdose. This resolved spontaneously within 24 hours without treatment. Local tissue reaction in the form of swelling (below 2 cm in diameter) at the injection site was commonly observed and resolved within 2 days.

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

Not applicable

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 containing the porcine circovirus type 2 ORF2 protein. The vaccine also contains inactivated *Mycoplasma hyopneumoniae*. It is intended to stimulate active immunity against PCV2 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: 2 years.
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.

5.4 Nature and composition of immediate packaging

High density polyethylene vials of 50 ml, of 100 ml and of 250 ml (25, 50 and 125 doses), with a chlorobutyl elastomer closure and sealed with an aluminium cap.

Cardboard box of 1 vial of 50 ml (25 doses), 100 ml (50 doses) or 250 ml (125 doses).
Cardboard box of 10 vials of 50 ml (25 doses) or 100 ml (50 doses).
Cardboard box of 4 vials of 250 ml (125 doses).

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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/2/15/190/001-006

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 06/11/2015.

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

{DD/MM/YYYY}

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

Suvaxyn Circo+MH RTU emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each 2 ml dose contains:

Inactivated recombinant chimeric porcine circovirus type 1 containing the porcine circovirus type 2 ORF2 protein	2.3-12.4 RP
Inactivated *Mycoplasma hyopneumoniae* strain P-5722-3	1.5-3.8 RP

3. PACKAGE SIZE

1 x 50 ml (25 doses)
1 x 100 ml (50 doses)
1 x 250 ml (125 doses)

10 x 50 ml (25 doses)
10 x 100 ml (50 doses)
4 x 250 ml (125 doses)

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/2/15/190/001 (1 x 50 ml)
EU/2/15/190/002 (1 x 100 ml)
EU/2/15/190/003 (1 x 250 ml)
EU/2/15/190/004 (10 x 50 ml)
EU/2/15/190/005 (10 x 100 ml)
EU/2/15/190/006 (4 x 250 ml)

15. BATCH NUMBER

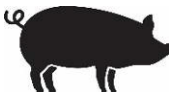
Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

HDPE vials (125 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn Circo+MH RTU emulsion for injection



2. STATEMENT OF ACTIVE SUBSTANCES

Each 2 ml dose contains:

Inactivated recombinant chimeric PCV type 1 containing the PCV type 2 ORF2 protein	2.3-12.4 RP
Inactivated *Mycoplasma hyopneumoniae* strain P-5722-3	1.5-3.8 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 (25 or 50 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn Circo+MH RTU

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Inactivated recombinant chimeric PCV type 1 containing the PCV type 2 ORF2 protein	2.3-12.4 RP
Inactivated *Mycoplasma hyopneumoniae* strain P-5722-3	1.5-3.8 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

Suvaxyn Circo+MH RTU 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 2 ORF2 protein	2.3 – 12.4 RP*
Inactivated *Mycoplasma hyopneumoniae,* strain P-5722-3	1.5 – 3.8 RP*

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

Adjuvant:	
MetaStim containing:	
Squalane	0.4% (v/v)
Poloxamer 401	0.2% (v/v)
Polysorbate 80	0.032% (v/v)
Excipient:	
Thiomersal	0.2 mg

White homogenous emulsion.
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.

3. Target species

Pigs (for fattening).

4. Indications for use

For active immunisation of pigs from 3 weeks of age against porcine circovirus type 2 (PCV2) to reduce viral load in blood and lymphoid tissues and faecal shedding caused by infection with PCV2.
For active immunization of pigs from 3 weeks of age against *Mycoplasma hyopneumoniae* to reduce lung lesions caused by infection with *M. hyopneumoniae*.

Onset of immunity: 3 weeks.
Duration of immunity: 23 weeks.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

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.

Fertility:
No information is available on the safety of this vaccine in breeding boars. Do not use in breeding boars.

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:
A transient increase in body temperature (on average 0.8 °C) was observed 4 hours after administration of a 2-fold overdose. This resolved spontaneously within 24 hours without treatment. Local tissue reaction in the form of swelling (below 2 cm in diameter) at the injection site was commonly observed and resolved within 2 days.

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[1] Injection site inflammation[2], Injection site pain[3], injection site reddening[3], injection site swelling[3]
Uncommon (1 to 10 animals / 1,000 animals treated):	Hypersensitivity reactions (e.g. depression, diarrhoea or vomiting)[4]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylaxis (severe allergic reaction)[5]

[1]Transient; observed during the first 24 hours after vaccination. On average 1° C but may exceed 2° C in individual pigs. This resolves spontaneously within 48 hours without treatment.
[2] Post-mortem examination of the injection site, performed 4 weeks after the administration of a repeated single dose of the vaccine very commonly revealed a mild lymphocytic-granulomatous inflammatory response.
[3] The area of local tissue reactions is in general below 2 cm in diameter and may last up to 2 days.

[4] Normally resolve without treatment.
[5] In case of such reactions, appropriate treatment is recommended.

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.
Single intramuscular injection in the neck behind the ear of one dose (2 ml) to pigs from 3 weeks of age.

9. Advice on correct administration

Shake well before administration and intermittently during the process of vaccination.
The vaccine is to be administered aseptically.
The use of a multi-dosing syringe is recommended. Use vaccination devices according to the manufacturer's instructions.
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.

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. The expiry date refers to the last day of that month.

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.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/15/190/001-006.

Cardboard box of 1 vial of 50 ml (25 doses), 100 ml (50 doses) or 250 ml (125 doses).
Cardboard box of 10 vials of 50 ml (25 doses) or 100 ml (50 doses).
Cardboard box of 4 vials of 250 ml (125 doses).

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{DD/MM/YYYY}

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

16. Contact details

Marketing authorisation 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:

België/Belgique/Belgien
Zoetis Belgium
Mercuriusstraat 20
BE-1930 Zaventem
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17. Other information

The vaccine contains an inactivated recombinant chimeric porcine circovirus type 1 containing the porcine circovirus type 2 ORF2 protein and inactivated *Mycoplasma hyopneumoniae.* It is intended to stimulate active immunity against PCV2 and *Mycoplasma hyopneumoniae* in pigs.