ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cirbloc M Hyo emulsion for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose contains:

Active substances:

Mycoplasma hyopneumoniae, strain 2940, inactivated	min. 184 AU*
Porcine circovirus type 2d, ORF2 capsid protein	min. 19.6 mcg

*AU: Antigen units as measured in potency test (ELISA)

Adjuvant:

Light liquid paraffin	277 µl

Excipients:

Qualitative composition of excipients and other constituents
Sorbitan trioleate
Polysorbate 80
Potassium chloride
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
Water for injections

Off-white emulsion. Greyish creaming and sedimentation may occur. Homogeneous emulsion after shaking.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (for fattening)

3.2 Indications for use for each target species

For the active immunisation of pigs to reduce:
- viraemia, virus load in lungs and lymphoid tissues, virus shedding caused by porcine circovirus type 2 (PCV2) infection,
- severity of lung lesions caused by *Mycoplasma hyopneumoniae* infection,
- the loss in body weight gain.

Onset of immunity:
PCV2: 2 weeks after vaccination
M. hyopneumoniae: 3 weeks after vaccination

Duration of immunity:
PCV2: 23 weeks after vaccination
M. hyopneumoniae: 23 weeks after vaccination

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.
In farms where PCV2 and *M. hyopneumoniae* vaccination of sows and gilts is performed during their late pregnancy and the high levels of MDA can be expected, the use of Cirbloc M Hyo may be delayed.

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:

To the user:
This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pigs (for fattening):

Very common (>1 animal / 10 animals treated):	Injection site swelling[1]
Very common (>1 animal / 10 animals treated):	Elevated temperature[2] Lethargy[2]

[1] Swellings of 0.2 cm to 2 cm diameter might occur when administration is performed with mass injector; they disappear spontaneously within nine days.
[2] Lethargy and increase in body temperature can occur four hours after vaccination, with a maximum of 1.7 °C at individual level and 0.5-0.78 °C as an average, resolving spontaneously by the next day.

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 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.

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.

Vaccinate pigs in the neck.
A single dose of 2 ml is given to pigs from 3 weeks of age onwards.

Allow it to reach room temperature (15 °C – 25 °C).
Shake well before use.
Apply usual aseptic procedures.

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

No data available.

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 product stimulates the development of active immunity against porcine circovirus type 2 and *Mycoplasma hyopneumoniae* in pigs.

The recombinant porcine circovirus type 2d antigen (ORF2 capsid protein) auto-assembles into virus-like-particles (VLPs).

The vaccine is able to reduce the loss in body weight gain in those farms where the level of PCV2 infection is high and the duration is long.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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: 10 hours.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Store in the original container.

Protect from light.

5.4 Nature and composition of immediate packaging

Low density polyethylene (LDPE) bottles of 50, 100, 250 or 500 ml sealed with rubber stopper and aluminium cap.

Pack sizes:
Cardboard box of 1 x 50 ml (1 x 25 doses)
Cardboard box of 10 x 50 ml (10 x 25 doses)

Cardboard box of 1 x 100 ml (1 x 50 doses)
Cardboard box of 10 x 100 ml (10 x 50 doses)
Cardboard box of 48 x 100 ml (48 x 50 doses)

Cardboard box of 1 x 250 ml (1 x 125 doses)
Cardboard box of 6 x 250 ml (6 x 125 doses)

Cardboard box of 1 x 500 ml (1 x 250 doses)
Cardboard box of 6 x 500 ml (6 x 250 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

Ceva-Phylaxia Co. Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/24/322/001-009

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 24/10/2024

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
CARTON BOX

50, 100, 250 or 500 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cirbloc M Hyo emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Mycoplasma hyopneumoniae, strain 2940, inactivated	min. 184 AU
Porcine circovirus type 2d, ORF2 capsid protein	min. 19.6 mcg

3. PACKAGE SIZE

1 x 50 ml
10 x 50 ml
1 x 100 ml
10 x 100 ml
48 x 100 ml
1 x 250 ml
6 x 250 ml
1 x 500 ml
6 x 500 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 within 10 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Store in the original container.

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

Ceva-Phylaxia Co. Ltd.

14. MARKETING AUTHORISATION NUMBERS

EU/2/24/322/001 1 x 50 ml
EU/2/24/322/002 10 x 50 ml
EU/2/24/322/003 1 x 100 ml
EU/2/24/322/004 10 x 100 ml
EU/2/24/322/005 48 x 100 ml
EU/2/24/322/006 1 x 250 ml
EU/2/24/322/007 6 x 250 ml
EU/2/24/322/008 1 x 500 ml
EU/2/24/322/009 6 x 500 ml

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100, 250 or 500 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cirbloc M Hyo emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Mycoplasma hyopneumoniae, strain 2940, inactivated	min. 184 AU
Porcine circovirus type 2d (ORF2 capsid protein)	min. 19.6 mcg

50 doses (100 ml)
125 doses (250 ml)
250 doses (500 ml)

3. TARGET SPECIES

Pigs (for fattening)

4. ROUTES OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: Zero days

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 10 hours.

7. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Store in the original container.

Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva-Phylaxia Co. Ltd.

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

50 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cirbloc M Hyo emulsion for injection

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Mycoplasma hyopneumoniae, strain 2940, inactivated	min. 184 AU
Porcine circovirus type 2d, ORF2 capsid protein	min. 19.6 mcg

25 doses (50 ml)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 10 hours.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Cirbloc M Hyo emulsion for injection for pigs

2. Composition

Each 2 ml dose contains:

Active substances:

Mycoplasma hyopneumoniae, strain 2940, inactivated	min. 184 AU*
Porcine circovirus type 2d, ORF2 capsid protein	min. 19.6 mcg

*AU: Antigen units as measured in potency test (ELISA)

Adjuvant:

Light liquid paraffin	277 µl

Off-white emulsion. Greyish creaming and sedimentation may occur. Homogeneous emulsion after shaking.

3. Target species

Pigs (for fattening)

4. Indications for use

For the active immunisation of pigs to reduce:
- viraemia, virus load in lungs and lymphoid tissues, virus shedding caused by porcine circovirus type 2 (PCV2) infection,
- severity of lung lesions caused by *Mycoplasma hyopneumoniae* infection,
- the loss in body weight gain.

Onset of immunity:
PCV2: 2 weeks after vaccination
M. hyopneumoniae: 3 weeks after vaccination

Duration of immunity:
PCV2: 23 weeks after vaccination
M. hyopneumoniae: 23 weeks after vaccination

5. Contraindications

None.

6. Special warnings

Special warnings:

Vaccinate healthy animals only.

In farms where PCV2 and *M. hyopneumoniae* vaccination of sows and gilts is performed during their late pregnancy and the high levels of MDA can be expected, the use of Cirbloc M Hyo may be delayed.

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:

To the user:
This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy or 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
No data available.

Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Pigs (for fattening)

Very common (>1 animal / 10 animals treated):	Injection site swelling[1]
Very common (>1 animal / 10 animals treated):	Elevated temperature[2] Lethargy[2]

[1] Swellings of 0.2 cm to 2 cm diameter might occur when administration is performed with mass injector; they disappear spontaneously within nine days.

[2] Lethargy and increase in body temperature can occur four hours after vaccination, with a maximum of 1.7 °C at individual level and 0.5-0.78 °C as an average, resolving spontaneously by the next day.

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 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.

Vaccinate pigs in the neck.
A single dose of 2 ml is given to pigs from 3 weeks of age onwards.

9. Advice on correct administration

Allow it to reach room temperature (15 °C – 25 °C).
Shake well before use.
Apply usual aseptic procedures.

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.
Store in the original container.

Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 10 hours.

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/2/24/322/001-009

Cardboard box of 1 x 50 ml (1 x 25 doses)
Cardboard box of 10 x 50 ml (10 x 25 doses)

Cardboard box of 1 x 100 ml (1 x 50 doses)
Cardboard box of 10 x 100 ml (10 x 50 doses)
Cardboard box of 48 x 100 ml (48 x 50 doses)

Cardboard box of 1 x 250 ml (1 x 125 doses)
Cardboard box of 6 x 250 ml (6 x 125 doses)

Cardboard box of 1 x 500 ml (1 x 250 doses)
Cardboard box of 6 x 500 ml (6 x 250 doses)

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 authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Ceva-Phylaxia Co. Ltd.
1107 Budapest, Szállás u. 5.
Hungary
Email: pharmacovigilance@ceva.com
Phone number: +800 35 22 11 51

17. Other information

The product stimulates the development of active immunity against porcine circovirus type 2 and *Mycoplasma hyopneumoniae* in pigs.

The recombinant porcine circovirus type 2d antigen (ORF2 capsid protein) auto-assembles into virus-like-particles (VLPs).

The vaccine is able to reduce the loss in body weight gain in those farms where the level of PCV2 infection is high and the duration is long.