ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Circovac emulsion and suspension for emulsion for injection for pig

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of reconstituted vaccine contains:

Active substance:
Inactivated porcine circovirus type 2 (PCV2) ..... ≥ 1.8 log10 ELISA Units

Adjuvant:
Light paraffin oil ..... 247 to 250.5 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Thiomersal	0.10 mg
Sorbitan oleate	
Polysorbate 80	
Polysorbate 85	
Sodium chloride	
Potassium dihydrogen phosphate	
Disodium phosphate dihydrate	
Water for injections	

Emulsion: white homogeneous emulsion
Suspension: homogeneous opalescent liquid

3. CLINICAL INFORMATION

3.1 Target species

Pig (gilts, sows and piglets from 3 weeks of age).

3.2 Indications for use for each target species

Piglets: Active immunisation of piglets to reduce faecal excretion of PCV2 and virus load in blood, and as an aid to reduce PCV2-linked clinical signs, including wasting, weight loss and mortality as well as to reduce virus load and lesions in lymphoid tissues associated with PCV2 infection.

Onset of immunity: 2 weeks
Duration of immunity: at least 23 weeks after vaccination.

Sows and gilts: Passive immunisation of piglets via the colostrum, after active immunisation of sows and gilts, to reduce lesions in lymphoid tissues associated with PCV2 infection and as an aid to reduce PCV2-linked mortality.

Duration of immunity: up to 5 weeks after transfer of passive antibodies through colostrum intake.

3.3 Contraindications

None

3.4 Special warnings

Vaccinate healthy animals only.

Piglets: The efficacy of the vaccine in the face of intermediate to high levels of maternally derived antibodies has been demonstrated.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Apply usual procedures for the handling of animals.
Apply usual aseptic procedures.

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

Pig:

Very common (>1 animal / 10 animals treated):	Injection site swelling[1], Injection site reddening[1], Injection site oedema[1] Injection site skin discolouration[2], Injection site granuloma[2], Injection site fibrosis[2], Injection site necrosis[2]
Rare (1 to 10 animals / 10,000 animals treated):	Hyperthermia[3], Apathy[4], Decreased appetite[4]
Very rare	Hypersensitivity reaction[5]

(<1 animal / 10,000 animals treated, including isolated reports):	Abortion

[1] Swelling (up to 2 cm^2 in average) and redness (up to 3 cm^2 in average), and in some cases oedema (up to 17 cm^2 in average). These reactions resolve spontaneously in maximum 4 days in average without any consequence on the health and the zootechnical performances.

[2] In sows at most 50 days after the vaccination limited lesions such as a discoloration and a granuloma as well as necrosis or fibrosis may occur. In piglets, due to the smaller dose volume used, less extended lesions and limited fibrosis may be observed at time of slaughter.

[3] Within the 2 days following the injection, an average increase in rectal temperature of up to 1.4 °C can occur. An increase in rectal temperature of higher than 2.5 °C, lasting less than 24 hours, may occur.

[4] Should resolve spontaneously.

[5] In such cases, an appropriate symptomatic treatment should be provided.

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

Pregnancy:

Can be used during pregnancy.

3.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine can be mixed with Hyogen (BE, NL: Hyogen J5; DK, SE: Mhyogen vet.) and administered to piglets at one injection site. When mixed with Hyogen, vaccinate only piglets from 3 weeks of age.

Onset of immunity: 3 weeks after vaccination when mixed with Hyogen.
Duration of immunity: 23 weeks when mixed with Hyogen.

In case of mixing with Hyogen, slight and transient local reactions may occur very commonly after the administration, mainly swelling (0.5 cm – 5 cm), mild pain and redness as well as in some cases oedema. These reactions resolve spontaneously within maximum 4 days. Transient lethargy may occur very commonly on the day of vaccination which resolves spontaneously within 1-2 days. An increase in individual rectal temperature of up to 2.5 °C may occur commonly lasting less than 24 hours. The above adverse reactions were observed in clinical studies.

When Circovac is used mixed with Hyogen the data available are not sufficient to exclude the interaction of maternally derived antibodies against *Mycoplasma hyopneumoniae* with vaccine uptake. Interaction with maternally derived antibodies is known and should be taken into consideration. It is recommended to delay vaccination in piglets with residual MDA against *Mycoplasma hyopneumoniae* at the age of 3 weeks.

The product literature of Hyogen should be consulted before mixed administration.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product, except when mixed with Hyogen. 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

Reconstitute immediately after removal from the refrigerator (or other cold storage).

To use the vaccine, shake vigorously the vial of antigen suspension and inject its content into the vial of emulsion containing adjuvant. Gently mix before use. The reconstituted vaccine is a homogeneous white emulsion.

When Circovac is used alone:

Piglets from 3 weeks of age:
Administer one 0.5 ml dose by deep intramuscular injection.

Gilts and sows:
Administer one 2 ml dose by deep intramuscular injection in accordance with the following vaccination scheme:

Basic vaccination:

- Gilts: One injection, followed 3 to 4 weeks later by a second injection, at least 2 weeks before mating. One further injection must be given, at least 2 weeks before farrowing.
- Sows: One injection, followed 3 to 4 weeks later by a second injection, at least 2 weeks before farrowing.

Revaccination:

- One injection at each gestation, at least 2 to 4 weeks before farrowing.

When Circovac is mixed with Hyogen:

The mixed use is restricted to the 100 doses (200 ml) presentations of Hyogen and to the 100 doses presentations (50 ml of reconstituted vaccine) of Circovac.

Piglets from 3 weeks of age:

Circovac	**Hyogen**
100 doses for piglets (50 ml of reconstituted suspension + emulsion)	100 doses (200 ml of vaccine) in 250 ml bottle

Vaccine devices should be used under aseptic conditions and in accordance with the device instructions provided by the manufacturer.

Prepare Circovac by vigorously shaking the vial of antigen suspension and injecting its content into the vial of emulsion containing adjuvant.
Mix 50 ml of Circovac and 200 ml of Hyogen and shake gently until a homogeneous white emulsion is obtained.
Administer one 2.5 ml dose of the mixture by intramuscular injection, in the side of the neck.
Use the entire vaccine mixture immediately after mixing.

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

No adverse reactions except those mentioned in section 3.6 were observed after the administration of a double dose of vaccine.

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: QI09AA07

Swine inactivated viral vaccine

The reconstituted vaccine contains an inactivated PCV2 in an oily adjuvant (o/w). It is intended to stimulate active immunity in gilts and sows to provide passive immunity in piglets, through colostrum intake.
When used in piglets, it stimulates active immunity against PCV2.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except emulsion supplied for use with the veterinary medicinal product and those mentioned in section 3.8 above.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after reconstitution: use within 3 hours

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Store in the original package in order to protect from light.

5.4 Nature and composition of immediate packaging

Suspension:

Type I glass vials (5 and 20 ml) with butyl elastomer closures and sealed with an aluminium cap.
Low density polyethylene (50 ml) bottle with butyl elastomer closures and sealed with an aluminium cap.
Emulsion:

Type I glass vials (10 and 50 ml) or polypropylene (50 ml) or low-density polyethylene (50 ml and 100 ml) bottles with nitrile elastomer closures and sealed with an aluminium cap.

Pack sizes

- Box containing 1 vial of suspension + 1 vial of emulsion: 5 dose size for gilts and sows, 20 dose size for piglets
- Box containing 10 vials of suspension + 10 vials of emulsion: 10 x 5 dose size for gilts and sows, 10 x 20 dose size for piglets
- Box containing 1 vial of suspension + 1 vial of emulsion: 25 dose size for gilts and sows, 100 dose size for piglets
- Box containing 10 vials of suspension + 10 vials of emulsion: 10 x 25 dose size for gilts and sows, 10 x 100 dose size for piglets
- Box containing 1 vial of suspension + 1 vial of emulsion: 50 dose size for gilts and sows, 200 dose size for piglets
- Box containing 10 vials of suspension + 10 vials of emulsion: 10 x 50 dose size for gilts and sows, 10 x 200 dose size for piglets.

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/2/07/075/001-010

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 21/06/2007

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 vial of suspension + 1 vial of emulsion corresponding to 10 ml of reconstituted product.
10 vials of suspension + 10 vials of emulsion corresponding to 10 x 10 ml of reconstituted product.
1 vial of suspension + 1 vial of emulsion corresponding to 50 ml of reconstituted product.
10 vials of suspension + 10 vials of emulsion corresponding to 10 x 50 ml of reconstituted product.
1 vial of suspension + 1 vial of emulsion corresponding to 100 ml of reconstituted product.
10 vials of suspension + 10 vials of emulsion corresponding to 10 x 100 ml of reconstituted product.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Circovac emulsion and suspension for emulsion for injection for pig

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml of reconstituted vaccine contains:

Inactivated porcine circovirus type 2 (PCV2) ..... ≥ 1.8 log10 ELISA Units

3. PACKAGE SIZE

1 vial of suspension + 1 vial of emulsion: 5 dose size for gilts and sows, 20 dose size for piglets
10 vials of suspension + 10 vials of emulsion: 10 x 5 dose size for gilts and sows, 10 x 20 dose size for piglets
1 vial of suspension + 1 vial of emulsion: 25 dose size for gilts and sows, 100 dose size for piglets
10 vials of suspension + 10 vials of emulsion: 10 x 25 dose size for gilts and sows, 10 x 100 dose size for piglets
1 vial of suspension + 1 vial of emulsion: 50 dose size for gilts and sows, 200 dose size for piglets
10 vials of suspension + 10 vials of emulsion: 10 x 50 dose size for gilts and sows, 10 x 200 dose size for piglets

4. TARGET SPECIES

Pig

5. INDICATIONS

Read the package leaflet before use.

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once diluted use within 3 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Store in the original package in order to 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/2/07/075/001-010

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL (Suspension)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Circovac suspension

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Porcine circovirus 2

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once diluted use within 3 hours.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL (Emulsion)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Circovac emulsion

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Light paraffin oil and thiomersal
After reconstitution contains PCV2.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once diluted use within 3 hours.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Circovac emulsion and suspension for emulsion for injection for pig

2. Composition

Each ml of reconstituted vaccine contains:

Active substance:
Inactivated porcine circovirus type 2 (PCV2) ..... ≥ 1.8 log10 ELISA Units

Adjuvant:
Light paraffin oil ..... 247 to 250.5 mg

Excipient:
Thiomersal 0.10 mg

Emulsion: white homogeneous emulsion
Suspension: homogeneous opalescent liquid

3. Target species

Pig (gilts, sows and piglets from 3 weeks of age).

4. Indications for use

Piglets: Active immunisation of piglets to reduce faecal excretion of PCV2 and virus load in blood, and as an aid to reduce PCV2 linked clinical signs, including wasting, weight loss and mortality as well as to reduce virus load and lesions in lymphoid tissues associated with PCV2 infection.

Onset of immunity: 2 weeks.
Duration of immunity: at least 23 weeks after vaccination.

Sows and gilts: Passive immunisation of piglets via the colostrum, after active immunisation of sows and gilts, to reduce lesions in lymphoid tissues associated with PCV2 infection and as an aid to reduce PCV2-linked mortality.

Duration of immunity: up to 5 weeks after transfer of passive antibodies through colostrum intake.

5. Contraindications

None.

6. Special warnings

Special warnings:

Vaccinate healthy animals only.

Piglets: The efficacy of the vaccine in the face of intermediate to high levels of maternally derived antibodies has been demonstrated.

Special precautions for safe use in the target species:

Apply usual procedures for the handling of animals.
Apply usual aseptic procedures.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

To the user:
This 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 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 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:

Can be used during pregnancy.

Interaction with other medicinal products and other forms of interaction:

Safety and efficacy data are available which demonstrate that this vaccine can be mixed with Hyogen / Hyogen J5 / Mhyogen vet. and administered to piglets at one injection site. When mixed with Hyogen / Hyogen J5 / Mhyogen vet., vaccinate only piglets from 3 weeks of age.
The product literature of Hyogen / Hyogen J5 / Mhyogen vet. should be consulted before mixed administration.

Onset of immunity: 3 weeks after vaccination when mixed with Hyogen / Hyogen J5 / Mhyogen vet.
Duration of immunity: 23 weeks when mixed with Hyogen / Hyogen J5 / Mhyogen vet..

In case of mixing with Hyogen / Hyogen J5 / Mhyogen vet., slight and transient local reactions may occur very commonly after the administration, mainly swelling (0.5 cm-5 cm), mild pain and redness as well as in some cases oedema. These reactions resolve spontaneously within maximum 4 days. Transient lethargy may occur very commonly on the day of vaccination which resolves spontaneously within 1-2 days. An increase in individual rectal temperature of up to 2.5 °C may occur commonly lasting less than 24 hours.
The above adverse reactions were observed in clinical studies.

When Circovac is used mixed with Hyogen / Hyogen J5 / Mhyogen vet. the data available are not sufficient to exclude the interaction of maternally derived antibodies against *Mycoplasma hyopneumoniae* with vaccine uptake. Interaction with maternally derived antibodies is known and should be taken into consideration. It is recommended to delay vaccination in piglets with residual MDA against *Mycoplasma hyopneumoniae* at the age of 3 weeks.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except when mixed with Hyogen / Hyogen J5 / Mhyogen vet.. 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 adverse reactions, except those mentioned in the section "Adverse Reactions" were observed after the administration of a double dose of vaccine.
Major incompatibilities:

Do not mix with any other veterinary medicinal product, except emulsion supplied for use with the product and Hyogen/ Hyogen J5 / Mhyogen vet.. Hyogen/ Hyogen J5 / Mhyogen vet. may be not authorised to use in certain Member States.

7. Adverse events

Pigs:

Very common (>1 animal / 10 animals treated):	Injection site swelling[1], Injection site reddening[1], Injection site oedema[1] Injection site skin discolouration[2], Injection site granuloma[2], Injection site fibrosis[2], Injection site necrosis[2]
Rare (1 to 10 animals / 10,000 animals treated):	Hyperthermia[3], Apathy[4], Decreased appetite[4]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction[5] Abortion

[1] Swelling (up to 2 cm^2 in average) and redness (up to 3 cm^2 in average), and in some cases oedema (up to 17 cm^2 in average). These reactions resolve spontaneously in maximum 4 days in average without any consequence on the health and the zootechnical performances.

[2] In sows at most 50 days after the vaccination limited lesions such as a discoloration and a granuloma, as well as necrosis or fibrosis may occur. In piglets, due to the smaller dose volume used, less extended lesions and limited fibrosis may be observed at time of slaughter.

[3] Within the 2 days following the injection, an average increase in rectal temperature of up to 1.4 °C can occur. An increase in rectal temperature of higher than 2.5 °C, lasting less than 24 hours, may occur.

[4] Should resolve spontaneously.

[5] In such cases, an appropriate symptomatic treatment should be provided.

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

Reconstitute immediately after removal from the refrigerator (or other cold storage).

Piglets from 3 weeks of age: Administer one 0.5 ml dose by intramuscular injection.

Gilts and sows: Administer one 2 ml dose by deep intramuscular injection in accordance with the following vaccination scheme:

Basic vaccination:

- Gilts: One injection, followed 3 to 4 weeks later by a second injection, at least 2 weeks before mating. One further injection must be given, at least 2 weeks before farrowing.
- Sows: One injection, followed 3 to 4 weeks later by a second injection, at least 2 weeks before farrowing.

Revaccination:

- One injection at each gestation, at least 2 to 4 weeks before farrowing.

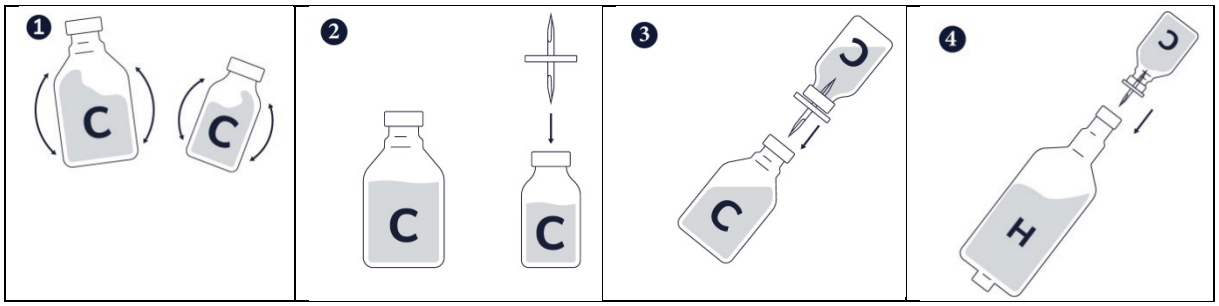
9. Advice on correct administration

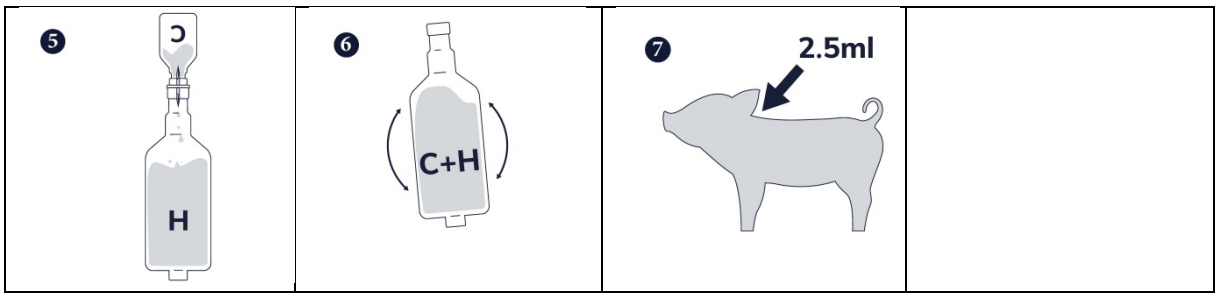
When Circovac is used alone:
To use the vaccine, shake vigorously the vial of antigen suspension and inject its content into the vial of emulsion containing adjuvant. Gently mix before use. The reconstituted vaccine is a homogeneous white emulsion.

When Circovac is mixed with Hyogen / Hyogen J5 / Mhyogen vet.**:**
Piglets from 3 weeks of age:

Circovac	Hyogen / Hyogen J5 / Mhyogen vet.
100 doses for piglets (50 ml of reconstituted suspension + emulsion)	100 doses (200 ml of vaccine) in 250 ml bottle

Vaccine devices should be used under aseptic conditions and in accordance with the device instructions provided by the manufacturer.
Step 1-3. Prepare Circovac (C) by shaking vigorously the vial of antigen suspension and injecting its content into the vial of emulsion containing adjuvant.
Step 4-6. Mix 50 ml of Circovac and 200 ml of Hyogen / Hyogen J5 / Mhyogen vet. (H) and shake gently until a homogeneous white emulsion is obtained.
Step 7. Administer one 2.5 ml dose of the mixture by intramuscular injection, in the side of the neck. Use the entire vaccine mixture immediately after mixing. Read also the product information of Hyogen / Hyogen J5 / Mhyogen vet. before use.





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 package in order to protect from light.

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

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/2/07/075/001-010

Pack sizes

- Box containing 1 vial of suspension + 1 vial of emulsion: 5 dose size for gilts and sows, 20 dose size for piglets
- Box containing 10 vials of suspension + 10 vials of emulsion: 10 x 5 dose size for gilts and sows, 10 x 20 dose size for piglets
- Box containing 1 vial of suspension + 1 vial of emulsion: 25 dose size for gilts and sows, 100 dose size for piglets
- Box containing 10 vials of suspension + 10 vials of emulsion: 10 x 25 dose size for gilts and sows, 10 x 100 dose size for piglets

- Box containing 1 vial of suspension + 1 vial of emulsion: 50 dose size for gilts and sows, 200 dose size for piglets
- Box containing 10 vials of suspension + 10 vials of emulsion: 10 x 50 dose size for gilts and sows, 10 x 200 dose size for piglets.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{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 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 reconstituted vaccine contains an inactivated PCV2 in an oily adjuvant (o/w). It is intended to stimulate active immunity in gilts and sows to provide passive immunity in piglets, through colostrum intake. When used in piglets, it stimulates active immunity against PCV2.