ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Circovac emulsion and suspension for emulsion for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of reconstituted vaccine contains:

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

Excipient:
Thiomersal .....0.10 mg

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

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion and suspension for emulsion for injection.
Pale opalescent liquid prior to reconstitution.
The reconstituted vaccine is a homogeneous white emulsion.

4. CLINICAL PARTICULARS

4.1 Target species

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

4.2 Indications for use, specifying the 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.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Sows: None.
Piglets: The efficacy of the vaccine in the face of intermediate to high levels of maternally derived antibodies has been demonstrated.

4.5 Special precautions for use

Special precautions for use in animals

Vaccinate only healthy animals.
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.

4.6 Adverse reactions (frequency and seriousness)

Vaccination may exceptionally cause hypersensitivity reactions. In such cases, an appropriate symptomatic treatment should be provided.

Slight and transient local reactions normally occur after the administration of one dose of vaccine, mainly 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.

In clinical studies, the post-mortem examination of the injection sites performed in sows at most 50 days after the vaccination revealed limited lesions such as a discoloration and a granuloma in the majority of animals, as well as necrosis or fibrosis in approximately half of the animals. In piglets, due to the smaller dose volume used, less extended lesions were observed in the laboratory trials whereas only limited fibrosis has uncommonly been observed at time of slaughter.

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

In rare cases, slight apathy or reduction in appetite may be observed, which should resolve spontaneously.

Exceptionally abortion may occur after vaccination.

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).

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy.

4.8 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.

4.9 Amounts to be administered and administration route

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No adverse reactions except those mentioned in section 4.6 were observed after the administration of a double dose of vaccine.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Swine inactivated viral vaccine
ATC vet code: QI09AA07

The reconstituted vaccine contains an inactivated porcine circovirus type 2 (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 porcine circovirus type 2.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Adjuvant emulsion:
Light paraffin oil
Thiomersal
Sorbitan oleate
Polysorbate 80
Polysorbate 85
Sodium chloride
Potassium dihydrogen phosphate
Disodium phosphate dihydrate
Water for injections

Antigen suspension:
Thiomersal
Sodium chloride
Potassium dihydrogen phosphate
Disodium phosphate dihydrate
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product, except emulsion supplied for use with the product and Hyogen.

6.3 Shelf life

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

6.4. 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.

6.5 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.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

CEVA-PHYLAXIA Co. Ltd.
Szállás u. 5.
1107 Budapest
Hungary

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/07/075/001-010

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21/06/2007
Date of last renewal: 10/05/2012

10. DATE OF REVISION OF THE TEXT

10/2022

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

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable

Hyogen may be not authorised to use in certain Member States.

ANNEX II

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

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY OR USE

C. STATEMENT OF THE MRLs

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

Name and address of the manufacturer of the biological active substance:

CEVA-Phylaxia Veterinary Biologicals Co. Ltd.
Szállás u. 5.
Budapest, 1107
Hungary

Name and address of the manufacturer responsible for batch release:

CEVA-Phylaxia Veterinary Biologicals Co. Ltd.
Szállás u. 5.
Budapest, 1107
Hungary

The printed package leaflet of the medicinal product must state the name and address of the manufacturer responsible for the release of the concerned batch.

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY OR USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

The active substance being a principle of biological origin intended to produce active immunity is not within the scope of Regulation (EC) 470/2009.

The excipients, including adjuvants, 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 are considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this product.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

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 pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml of reconstituted vaccine contains:
Active substance:
Inactivated porcine circovirus type 2 (PCV2) ..... ≥ 1.8 log10 ELISA Units
Excipient:
Thiomersal .....0.10 mg
Adjuvant:
Light paraffin oil ..... 247 to 250.5 mg

3. PHARMACEUTICAL FORM

Emulsion and suspension for emulsion for injection.

4. 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

5. TARGET SPECIES

Pigs

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous – read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Use within 3 hours after mixing.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated (2 °C-8 °C). Protect from light.

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

Read the package leaflet before use.

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

CEVA-PHYLAXIA Co. Ltd.
Szállás u. 5.
1107 Budapest
Hungary

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/07/075/001 1 vial of suspension + 1 vial of emulsion: 5 dose size for gilts and sows, 20 dose size for piglets
EU/2/07/075/002 10 vials of suspension + 10 vials of emulsion: 10 x 5 dose size for gilts and sows, 10 x 20 dose size for piglets
EU/2/07/075/003 1 vial of suspension + 1 vial of emulsion: 25 dose size for gilts and sows, 100 dose size for piglets
EU/2/07/075/004 10 vials of suspension + 10 vials of emulsion: 10 x 25 dose size for gilts and sows, 10 x 100 dose size for piglets
EU/2/07/075/005 1 vial of suspension + 1 vial of emulsion: 25 dose size for gilts and sows, 100 dose size for piglets
EU/2/07/075/006 10 vials of suspension + 10 vials of emulsion: 10 x 25 dose size for gilts and sows, 10 x 100 dose size for piglets
EU/2/07/075/007 1 vial of suspension + 1 vial of emulsion: 1 x 25 dose size for gilts and sows, 1 x 100 dose size for piglets
EU/2/07/075/008 10 vials of suspension + 10 vials of emulsion: 10 x 25 dose size for gilts and sows, 10 x 100 dose size for piglets
EU/2/07/075/009 1 vial of suspension + 1 vial of emulsion: 1 x 50 dose size for gilts and sows, 1 x 200 dose size for piglets
EU/2/07/075/010 10 vials of suspension + 10 vials of emulsion: 10 x 50 dose size for gilts and sows, 10 x 200 dose size for piglets

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Suspension

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Circovac suspension

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Porcine circovirus 2

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

Sows: 5 doses, piglets: 20 doses
Sows: 25 doses, piglets: 100 doses
Sows: 50 doses, piglets: 200 doses

4. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

5. WITHDRAWAL PERIOD(S)

Read the package leaflet before use.

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Emulsion

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Circovac emulsion

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Light paraffin oil and thiomersal
After reconstitution contains PCV2.

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

Sows: 5 doses, piglets: 20 doses
Sows: 25 doses, piglets: 100 doses
Sows: 50 doses, piglets: 200 doses

4. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
IM.

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

Circovac emulsion and suspension for 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 authorisation holder:

CEVA-Phylaxia Veterinary Biologicals Co. Ltd., Szállás u. 5., Budapest, 1107, Hungary

Manufacturer for batch release:

CEVA-Phylaxia Veterinary Biologicals Co. Ltd., Szállás u. 5., Budapest, 1107, Hungary

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Circovac
Emulsion and suspension for emulsion for injection for pigs

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

Pale opalescent liquid prior to reconstitution

Each ml of reconstituted vaccine contains:
Active substance:
Inactivated porcine circovirus type 2 (PCV2) ..... ≥ 1.8 log10 ELISA Units
Excipient:
Thiomersal .....0.10 mg
Adjuvant:
Light paraffin oil ..... 247 to 250.5 mg

4. INDICATION(S)

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. ADVERSE REACTIONS

Vaccination may exceptionally cause hypersensitivity reactions. In such cases, an appropriate symptomatic treatment should be provided.

Slight and transient local reactions normally occur after the administration of one dose of vaccine, mainly 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 a maximum of 4 days on average, without any consequence on the health and the zootechnical performance.

In clinical studies, post-mortem examination of the injection sites performed in sows at most 50 days after the vaccination revealed limited lesions such as a discoloration and a granuloma in the majority of animals as well as necrosis or fibrosis (in approximately half of the animals). In piglets, due to the smaller dose volume used, less extended lesions were observed in the laboratory trials whereas only limited fibrosis has uncommonly been observed at time of slaughter.

Within the 2 days following the injection, an average increase in rectal temperature up to 1.4 °C can occur. Rarely, an increase in rectal temperature of higher than 2.5 °C, lasting less than 24 hours, may occur. In rare cases, slight apathy or reduction in appetite may be observed, which should resolve spontaneously.

Exceptionally abortion may occur after vaccination.

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 serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

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

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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:

<u>Basic vaccination:</u>
- 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.

<u>Revaccination:</u>
- One injection at each gestation, at least 2 to 4 weeks before farrowing.

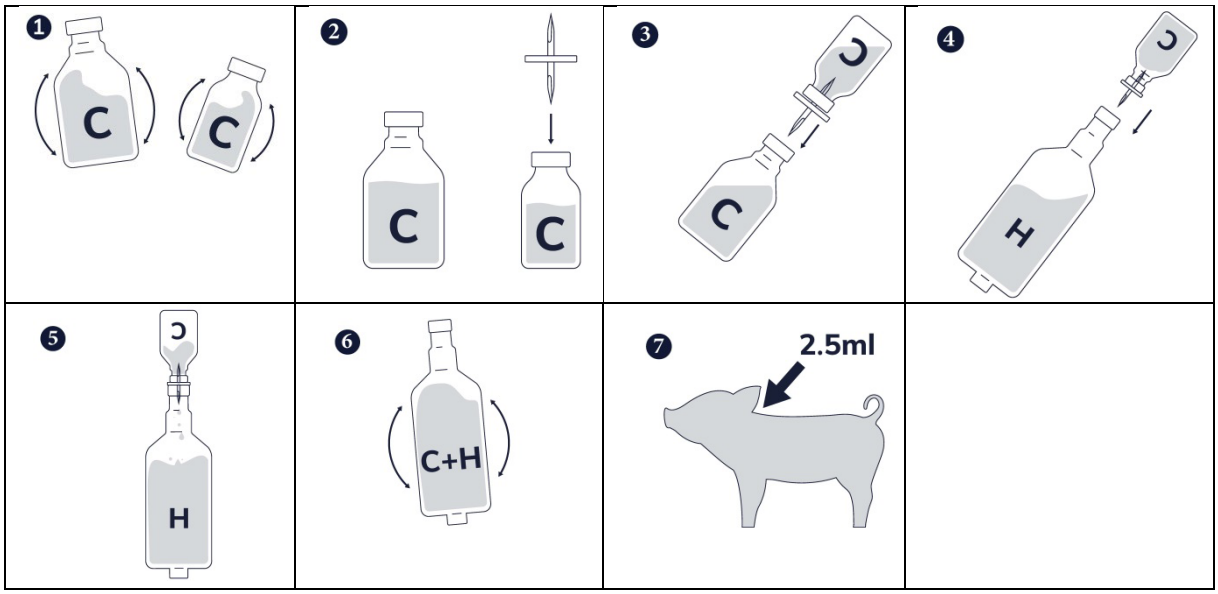
9. ADVICE ON CORRECT ADMINISTRATION

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 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).
Store in the original package in order to protect from light.
Use within 3 hours after mixing.
Do not use after the expiry date stated on the label after EXP.

12. SPECIAL WARNING(S)

Special warnings for each target species
The efficacy of the vaccine in the face of intermediate to high levels of maternally derived antibodies in piglets has been demonstrated.

Special precautions for use in animals
Vaccinate only healthy animals.
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.

Interactions with other medicinal products and other forms of interactions:

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 (symptoms, emergency procedures, antidotes):
No adverse reactions, except those mentioned in the section "Adverse Reactions" were observed after the administration of a double dose of vaccine.

Incompatibilities:
Do not mix with any other veterinary medicinal product, except emulsion supplied for use with the product and Hyogen / Hyogen J5 / Mhyogen vet..

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

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 reconstituted vaccine contains an inactivated porcine circovirus type 2 (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 porcine circovirus type 2.

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.
Not all pack sizes may be marketed.

Hyogen / Hyogen J5 / Mhyogen vet. may be not authorised to use in certain Member States.