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 veterinary medicinal 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 (gilts, sows and piglets from 3 weeks of age):

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 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 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: at least 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 shaking vigorously 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 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 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 product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.
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 Animal Health Ltd

7. MARKETING AUTHORISATION NUMBER

Vm 15052/5027

8. DATE OF FIRST AUTHORISATION

21 June 2007

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

July 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall
Approved: 04 November 2025