

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)..... $\geq 1.8 \log_{10}$ ELISA Units

Excipient:

Thiomersal0.10 mg

Adjuvant:

Light paraffin oil247 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 cm² in average) and redness (up to 3 cm² in average), and in some cases oedema (up to 17 cm² 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 reactions)
- 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 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 mix 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) |

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.

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 Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 15052/5027

9. DATE OF FIRST AUTHORISATION

21 June 2007

10. DATE OF REVISION OF THE TEXT

January 2024

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