Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Cirbloc emulsion for injection for pigs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (2 ml) contains:

Active substance:
Inactivated porcine circovirus (PCV) type 2b, strain Rm: ≥1,100 AU*

Adjuvants:

Light liquid paraffin	157 mg
Escherichia coli J5 LPS	2,500 – 38,000 EU**

Preservative:

Thiomersal	50 µg

* Antigenic Units as determined in the *in-vitro* potency test (ELISA)
** Endotoxin Units

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Emulsion for injection
Off-white, homogeneous emulsion.

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs (pigs for fattening)

4.2 Indications for use, specifying the target species

For the active immunization of fattening pigs from 3 weeks of age, to reduce viraemia, virus load in lymphoid tissues and virus shedding caused by porcine circovirus type 2 (PCV2) infection. To reduce weight loss associated with PCV2 infection during the fattening period.

Onset of immunity: 3 weeks after vaccination
Duration of immunity: 24 weeks after vaccination

4.3 Contraindications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
Vaccinate only healthy animals.

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

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

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 and 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)

A transient mean increase in body temperature of approximately 1.5°C is very common on the day of vaccination as shown in safety studies. In individual cases the maximum increase may reach 2^{o}C, but the body temperature returns to normal levels within 12 - 24 hours.
A local reaction at the site of injection in the form of slight swelling and reddish colorization with a diameter up to 5 cm was very commonly observed during the safety studies, which lasts in general for not longer than three to four days. These reactions are of transient nature and do not need further treatment.
Diarrhoea is very common post vaccination as observed in safety studies.
Immediate, mild hypersensitivity-like reactions uncommonly occur after vaccination in studies resulting in transient clinical signs such as vomiting. These clinical signs normally resolve without treatment.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 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.

4.9 Amounts to be administered and administration route

For intramuscular use.
Vaccinate pigs in the side of their neck.
Administer a single dose of 2 ml from 3 weeks of age.
Shake well before use.
Use sterile syringe and needle, respect aseptic conditions of vaccination.
The vaccine should not be used if the appearance of the product is not off-white, homogeneous emulsion after shaking.

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

No data available.

4.11 Withdrawal Period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated viral vaccines for pigs – porcine circovirus.
ATCvet code: QI09AA07.

Inactivated whole virus vaccine based on an immunogenic PCV2b strain. This antigen is incorporated in an adjuvant for stimulation of immunity, based on a combination of light liquid paraffin and cell free *Escherichia coli* J5 LPS. The vaccine stimulates the development of active immunity against porcine circovirus type 2.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Light liquid paraffin
Sorbitan trioleate
Polysorbate 80
Escherichia coli J5 LPS (lipopolysaccharide)
Thiomersal
Sodium chloride
Potassium chloride
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
Water for injection

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 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

6.4 Special precautions for storage

Store and transport refrigerated (2°C – 8°C).
Do not freeze.
Protect from light.

6.5 Nature and composition of immediate packaging

Low density polyethylene bottles sealed with rubber stopper and aluminium cap.
1 x 50 ml, 1 x 100 ml, 1 x 250 ml, 1 x 500 ml, 5 x 50 ml, 5 x 100 ml, 6 x 250 ml, 6 x 500 ml, 10 x 50 ml, 10 x 100 ml, 10 x 250 ml or 10 x 500 ml bottles in a carton box.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10463/001/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st March 2017

10 DATE OF REVISION OF THE TEXT