

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Circogen 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:  $\geq 1,100$  AU\*

**Adjuvants:**

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

**Preservative:**

Thiomersal	50 $\mu$ g
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\* 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°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. 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.  
1x50 ml, 1x100 ml, 1x250 ml, 1x500 ml, 5x50 ml, 5x100 ml, 6x250 ml, 6x500 ml,  
10x50 ml, 10x100 ml, 10x250 ml or 10x500 ml bottles in a carton box.  
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 product should be disposed of in accordance with local requirements.

## **7. MARKETING AUTHORISATION HOLDER**

Ceva Animal Health Ltd  
Unit 3, Anglo Office Park  
White Lion Road  
Amersham  
Buckinghamshire  
HP7 9FB

## **8. MARKETING AUTHORISATION NUMBER**

Vm 15052/4087

## **9. DATE OF FIRST AUTHORISATION**

24 January 2017

**10. DATE OF REVISION OF THE TEXT**

January 2017

**Approved: 24/01/2017**

A handwritten signature in black ink, appearing to read 'J. J. J.', is positioned below the approval date.