

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE**

**1x50, 1x100, 1x250, 1x500, 5x50, 5x100, 6x250, 6x500, 10x50, 10x100, 10x250, 10x500, ml carton box  
100, 250, 500 ml bottle**

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

Circogen emulsion for injection for pigs

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Each dose (2 ml) contains:  
Inactivated porcine circovirus (PCV) type 2b, strain Rm:  $\geq 1,100$  Antigenic Unit  
Oil adjuvant  
Thiomersal 50  $\mu\text{g}$

**3. PHARMACEUTICAL FORM**

Emulsion for injection

**4. PACKAGE SIZE**

50 ml  
100 ml  
250 ml  
500 ml  
5x50 ml  
5x100 ml  
6x250 ml  
6x500 ml  
10x50 ml  
10x100 ml  
10x250 ml  
10x500 ml

**5. TARGET SPECIES**

Pigs for fattening

**6. INDICATION(S)**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

For intramuscular use.  
Read the package leaflet before use and disposal.

**8. WITHDRAWAL PERIOD**

Withdrawal period: Zero days.

**9. SPECIAL WARNING(S), IF NECESSARY**

Accidental injection is dangerous.

**10. EXPIRY DATE**

EXP {month/year}  
Once broached, use by 10 hours.

**11. SPECIAL STORAGE CONDITIONS**

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

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

Disposal: read package leaflet

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

**16. MARKETING AUTHORISATION NUMBER**

Vm 15052/4087

**17. MANUFACTURER’S BATCH NUMBER**

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

50ml bottle

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

Circogen emulsion for injection for pigs

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

Inactivated PCV2b, strain Rm: 1,100 Antigenic Unit / dose

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

50 ml

**4. ROUTE(S) OF ADMINISTRATION**

IM

**5. WITHDRAWAL PERIOD**

Withdrawal period: Zero days.

**6. BATCH NUMBER**

Lot {number}

**7. EXPIRY DATE**

EXP {month/year}  
Once broached use by 10 hours.

**8. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

## **B. PACKAGE LEAFLET**

**PACKAGE LEAFLET FOR:**  
Circogen 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 Animal Health Ltd  
Unit 3, Anglo Office Park  
White Lion Road  
Amersham  
Buckinghamshire  
HP7 9FB

Manufacturer responsible for batch release:

Ceva-Phylaxia Co. Ltd.  
1107 Budapest Szállás u. 5.  
Hungary

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Circogen emulsion for injection for pigs

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

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

\*\* Endotoxin Units

Off-white, homogeneous emulsion.

The vaccine should not be used if the appearance of the product is not off-white, homogeneous emulsion after shaking.

**4. INDICATION(S)**

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

## **5. CONTRAINDICATIONS**

None.

## **6. ADVERSE REACTIONS**

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).

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

## **7. TARGET SPECIES**

Pigs (pigs for fattening)

## **8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION**

For intramuscular use.

Vaccinate pigs in the side of their neck.

Administer a single dose of 2 ml from 3 weeks of age.

## **9. ADVICE ON CORRECT ADMINISTRATION**

Shake well before use.

Use sterile syringe and needle, respect aseptic conditions of vaccination.

## **10. WITHDRAWAL PERIOD**

Zero days.

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.  
Store and transport refrigerated (2°C – 8°C).  
Do not freeze.  
Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label.

Shelf life after first opening the container: 10 hours

## **12. SPECIAL WARNING(S)**

Special warnings for each target species:

None.

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.

Pregnancy and lactation:

Not applicable.

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.

Overdose (symptoms, emergency procedures, antidotes):

No data available.

Incompatibilities:

Do not mix with any other veterinary medicinal product.

**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 product should be disposed of in accordance with local requirements.

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

MM/YYYY

**15. OTHER INFORMATION**

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.

Pack sizes:

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.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

**Approved: 24/01/2017**

