

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1 X OR 5 X 100 ML BOX LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Coglapix suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (2 ml) contains:

Actinobacillus pleuropneumoniae inactivated serotype 1(strain NT3) and
Actinobacillus pleuropneumoniae inactivated serotype 2(strains PO, U3, B4, SZ II)
expressing

ApxI toxoid min. 28.9 ELISA unit / ml

ApxII toxoid min. 16.7 ELISA unit / ml

ApxIII toxoid min. 6.8 ELISA unit / ml

3. PACKAGE SIZE

100 ml

5 x 100 ml

4. TARGET SPECIES

Pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use

7. WITHDRAWAL PERIODS

Withdrawal period:

Zero days.

8. EXPIRY DATE

Exp: {mm/yyyy}

Once broached use within 10 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated

Do not freeze.

Protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Sante Animale

14. MARKETING AUTHORISATION NUMBERS

Vm 14966/5063

Vm 14966/3062

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ML CONTAINER LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Coglapix suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (2 ml) contains:

Actinobacillus pleuropneumoniae inactivated serotype 1 (strain NT3) and
Actinobacillus pleuropneumoniae inactivated serotype 2 (strains PO, U3, B4, SZ II)
expressing
ApxI toxoid min. 28.9 ELISA unit / ml
ApxII toxoid min. 16.7 ELISA unit / ml
ApxIII toxoid min. 6.8 ELISA unit / ml

3. TARGET SPECIES

Pigs

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.
Intramuscular use

5. WITHDRAWAL PERIODS

Withdrawal period:
Zero days.

6. EXPIRY DATE

Exp: {mm/yyyy}
Once broached use within 10 hours.

7. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated
Do not freeze.
Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Sante Animale

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Coglapix suspension for injection for pigs

2. Composition

Each dose (2 ml) of vaccine contains:

Active substances:

Actinobacillus pleuropneumoniae inactivated serotype 1 (strain NT3) and
Actinobacillus pleuropneumoniae inactivated serotype 2 (strains PO, U3, B4, SZ II)
expressing

ApxI toxoid min. 28.9 ELISA unit / ml*

ApxII toxoid min. 16.7 ELISA unit / ml

ApxIII toxoid min. 6.8 ELISA unit / ml

*Elisa unit / ml calculated serological titre in sera of immunised rabbits

Adjuvant:

Aluminium hydroxide (Al³⁺) 4.85 mg

Thiomersal max 0.22 mg

Greyish-white, opaque liquid.

3. Target species

Pigs

4. Indications for use

For the active immunisation of pigs as an aid to control pleuropneumonia caused by *Actinobacillus pleuropneumoniae* serotypes 1 and 2, by reducing the clinical signs and lung lesions associated with the disease.

Onset of immunity: 21 days following second vaccination

Duration of immunity: 16 weeks following second vaccination

5. Contraindications

None

6. Special warnings

Special warnings:

No information is available on the efficacy of the vaccine in animals with maternally derived antibodies. However, these antibodies are usually not present in piglets at the age of vaccination.

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.

Special precautions for the protection of the environment:

Not Applicable.

Pregnancy and lactation:

Do not use during pregnancy and lactation.

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:

Administration of a double dose caused no other reactions than those described in 7 (adverse events); however, severity of the signs was increased e.g. transient and mild swelling of maximum 3x3 cm at the site of injection, regressing, but persisting for at least 14 days; body temperature increases of up to 2.6°C for 2 hours on days 1 or 2 after vaccination.

Major incompatibilities:

Do not mix with any other veterinary medicinal product.

7. Adverse events

Pigs

Very common (>1 animal / 10 animals treated):	Injection site swelling ¹
Common (1 to 10 animals / 100 animals treated):	Elevated temperature ²
Uncommon (1 to 10 animals / 1000 animals treated)	Prostration ³
Very rare (<1 animal / 10000 animals treated)	Anaphylactic type reaction ⁴

¹ of maximum 2x3.2 cm persisting for at least 8 days

² Up to 1.8 °C for 2 hours on days 1 or 2 after vaccination.

³ For a view hours after vaccination.

⁴ Appropriate symptomatic treatment recommended.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Intramuscular use.

The preferred site of administration is the neck region.

Vaccination schedule: 2 doses administered to animals from 7 weeks of age with an interval of 3 weeks between doses.

9. Advice on correct administration

Shake well before use.

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

10. Withdrawal periods

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 after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

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 applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

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

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 14966/5063

Vm 14966/3062

Pack sizes:

Cardboard box containing 1 vial of 100 ml

Cardboard box containing 5 vials of 100 ml

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder:

Ceva Sante Animale

8 rue de Logrono

33500 Libourne

France

Manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Ceva Animal Health Ltd

Explorer House

Mercury Park

Wycombe Lane

Wooburn Green

High Wycombe

Buckinghamshire

HP10 0HH

United Kingdom

Ceva-Phylaxia Co. Ltd.
1107 Budapest Szállás u. 5.
Hungary
Email: pharmacovigilance@ceva.com
Phone number: +800 35 22 11 51

17. Other information

The vaccine contains inactivated *Actinobacillus pleuropneumoniae* bacteria. The total quantity is 20×10^9 inactivated germs per dose.

Strain NT3 belongs to the serotype 1, expressing ApxI whereas strains SzII, PO, U3 and B4 belong to the serotype 2, expressing ApxIII. All the strains express also ApxII.

Vaccinated pigs develop active immunity against disease caused by serotype 1 or 2 of *Actinobacillus pleuropneumoniae*. Efficacy was demonstrated under laboratory but not under field conditions.

POM-V

Gavin Hall
Approved: 24 October 2025