SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Coglapix suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE 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 (Al^{3+}) 4.85 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the pharmaceutical product**
Thiomersal	max 0.22 mg
Sodium hydroxide	
Sodium chloride	
Water for injection	

Greyish-white, opaque liquid.

3. CLINICAL INFORMATION

3.1 Target species

Pigs.

3.2 Indications for use for each target species

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

3.3 Contraindications

None.

3.4 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.

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

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.

3.6 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Do not use during pregnancy and lactation.

3.8 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.

3.9 Administration routes and dosage

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.

Shake well before use.
Use sterile syringe and needle, respect aseptic conditions of vaccination.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Administration of a double dose caused no other reactions than those described in 3.6 (adverse reactions); 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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI09AB07

Porcine actionobacillosis vaccine, inactivated.

The vaccine contains inactivated *Actinobacillus pleuropneumoniae* bacteria. The total quantity is 20 x 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf life after first opening the immediate packaging: 10 hours.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Low density polyethylene vial of 100 ml volume, sealed with bromobutyl rubber stopper and aluminium cap.

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.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd

7. MARKETING AUTHORISATION NUMBERS

Vm 015052/5077
Vm 15052/3042

8. DATE OF FIRST AUTHORISATION

21 October 2015

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

May 2025

10. 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.

Gavin Hall

Approved: 22 May 2025