ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Coglapix suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose 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
Excipient:
Thiomersal max 0.22 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection
Greyish-white, opaque liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs

4.2 Indications for use, specifying the 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

4.3 Contraindications

None.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals

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.

4.6 Adverse reactions (frequency and seriousness)

Adverse reactions to the vaccine include:
- a transient and mild swelling of maximum 2x3.2 cm is very common at the site of injection, persisting for at least 8 days.
- body temperature commonly increases of up to 1.8°C for 2 hours on days 1 or 2 after vaccination.

Vaccinated pigs may show signs of prostration for a few hours after vaccination, however, this is uncommon.

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

4.7 Use during pregnancy, lactation or lay

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

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

Intramuscular use.
The preferred site of administration is the neck region.
Dose: 2ml
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.

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

Administration of a double dose caused no other reactions than those described in 4.6 (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.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Suidae, inactivated bacterial vaccines for pigs..
ATC vet code: QI09AB07

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium-hydroxide
Thiomersal
Sodium hydroxide
Sodium chloride
Water for injection

6.2 Major 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: 18 months
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 vial of 100 ml volume, sealed with bromobutyl rubber stopper and aluminium cap.

Cardboard box containing 1 vial of 100 ml
Cardboard box containing 5 vials of 100 ml

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 products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

{Name
Address
Country}
<{Tel.}>
<{Fax}>
<{E-mail}>

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: <{DD/MM/YYYY}><{DD month YYYY}.
Date of last renewal: <{DD/MM/YYYY}> <{DD month YYYY}.

10 DATE OF REVISION OF THE TEXT

{MM/YYYY}

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1 x or 5 x 100ml box label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Coglapix suspension for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Each 2 ml dose 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. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

100 ml
5 x 100 ml

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use
Shake well before use.
Read the package leaflet before use and disposal.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use and disposal.

10. EXPIRY DATE

EXP:
Once broached use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

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

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

Read the package leaflet before use and disposal.

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

{Name
Address
Country}
<{Tel.}>
<{Fax}>
<{E-mail}>

16. MARKETING AUTHORISATION NUMBER(S)

MA number

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100ml container label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Coglapix suspension for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Each 2 ml dose 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. PHARMACEUTICAL FORM

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

IM
Shake well before use.
Read the package leaflet before use and disposal.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:
Once broached use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

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

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

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"

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

{Name
Address
Country}
<{Tel.}>
<{Fax}>
<{E-mail}>

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot:

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Coglapix suspension 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:

Manufacturer responsible for batch release:
Ceva-Phylaxia Co. Ltd.
1107 Budapest, Szállás u. 5. Hungary

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Coglapix suspension for injection for pigs

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

Each 2 ml dose 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
Excipient: Thiomersal max 0.22 mg

4. INDICATION(S)

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. ADVERSE REACTIONS

Adverse reactions to the vaccine include:
- a transient and mild swelling of maximum 2x3.2 cm is very common at the site of injection, persisting for at least 8 days.

- body temperature commonly increases of up to 1.8°C for 2 hours on days 1 or 2 after vaccination.

Vaccinated pigs may show signs of prostration for a few hours after vaccination, however, this is uncommon.

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

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 inform your veterinary surgeon.

7. TARGET SPECIES

Pigs

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

Intramuscular use.
The preferred site of administration is the neck region.
Dose: 2 ml
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 PERIOD(S)

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.
Shelf life after first opening the container: 10 hours.
Do not use this veterinary medicinal product after the expiry date which is stated on the label.

12. SPECIAL WARNING(S)

Special warnings for each target species:
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.

Special precautions for use in animals:
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.

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 (symptoms, emergency procedures, antidotes):
Administration of a double dose caused no other reactions than those described at 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.

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 products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pharmacotherapeutic group: Actinobacillus / Haemophilus vaccine.
ATCvet code: QI09AB07

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.

Presentations:
Low density polyethylene vial of 100 ml volume, sealed with bromobutyl rubber stopper and aluminium cap.
Cardboard box containing 1 vial of 100 ml

Cardboard box containing 5 vials of 100 ml

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.