ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box (**10 doses)**
Cardboard box (**25 doses)**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enteroporc COLI AC lyophilisate and suspension for suspension for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

One dose (2 ml) contains:

Clostridium perfringens type A/C toxoids:

alpha toxoid	≥ 125 rU/ml
beta1 toxoid	≥ 3354 rU/ml
beta2 toxoid	≥ 794 rU/ml

Inactivated fimbrial adhesins of *Escherichia coli*:

F4ab	≥ 23 rU/ml
F4ac	≥ 19 rU/ml
F5	≥ 13 rU/ml
F6	≥ 37 rU/ml

3. PHARMACEUTICAL FORM

Lyophilisate and suspension for suspension for injection

4. PACKAGE SIZE

10 doses
25 doses

5. TARGET SPECIES

Pigs (pregnant sows and gilts)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life after reconstitution: 8 hours at 2 -8 °C. Once the reconstituted vaccine is removed from storage at 2-8 °C, it should be used immediately.

11. SPECIAL STORAGE CONDITIONS

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

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
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 15052/5002

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial (10 doses) Lyophilisate
Vial (25 doses) Lyophilisate

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enteroporc COLI AC lyophilisate

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

C. perfringens toxoids

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

10 doses
25 doses

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Shelf life after reconstitution: 8 hours at 2 - 8 °C. Once the reconstituted vaccine is removed from storage at 2-8 °C, it should be used immediately.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial (10 doses) suspension
Vial (25 doses) suspension

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enteroporc COLI AC suspension

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

E. coli fimbrial adhesins

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

10 doses
25 doses

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Enteroporc COLI AC lyophilisate and suspension for 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:
Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

Manufacturer responsible for batch release:
IDT Biologika GmbH
Am Pharmapark
06861 Dessau-Rosslau
Germany

OR

CEVA-Phylaxia Veterinary Biologicals Co. Ltd.
Szállás utca 5
1107 Budapest
Hungary

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enteroporc COLI AC
lyophilisate and suspension for suspension for injection for pigs

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

One dose (2 ml) contains:

Active substances:

Lyophilisate:
Clostridium perfringens type A/C toxoids:

alpha toxoid	≥ 125 rU/ml*
beta1 toxoid	≥ 3354 rU/ml*
beta2 toxoid	≥ 794 rU/ml*

Suspension:
Inactivated fimbrial adhesins of *Escherichia coli*:

F4ab	≥ 23 rU/ml*
F4ac	≥ 19 rU/ml*
F5	≥ 13 rU/ml*
F6	≥ 37 rU/ml*

* toxoid content and fimbrial adhesins content in relative units per ml, determined in ELISA against an internal standard

Adjuvant:

Aluminium (as hydroxide)	2.0 mg/ml

Beige to brown lyophilisate.
Yellowish suspension.

4. INDICATIONS

For the passive immunisation of progeny by active immunisation of pregnant sows and gilts to reduce:

- Clinical signs (severe diarrhoea) and mortality caused by *E. coli* strains expressing the adhesins F4ab, F4ac, F5 and F6,
- Clinical signs (diarrhoea) during the first days of life associated with *Clostridium perfringens* type A expressing alpha and beta2 toxins.
- Clinical signs and mortality associated with haemorrhagic and necrotizing enteritis caused by *Clostridium perfringens* type C expressing beta1 toxin

Onset of immunity (after uptake of colostrum):
E. coli F4ab, F4ac, F5, F6: within 12 hours after birth
C. perfringens type A and C: First day of life

Duration of immunity:

E coli F4ab, F4ac, F5, F6:	first days of life
C. perfringens type A:	14 days of life
C. perfringens type C:	21 days of life

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

A transient increase in body temperature (mean 0.5 °C, in individual pigs up to 2 °C) occurred very commonly on the day of vaccination which returned to normal within 24 hours.
A transient swelling and redness at the injection site (mean 2.8 cm, in individual pigs up to 8 cm) was very commonly observed which disappeared without treatment within 7 days.
A slightly depressed behaviour was commonly observed on the days of vaccination.

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 (pregnant sows and gilts).

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

Intramuscular use.

Inject one dose (2 ml) of vaccine onto neck muscles in the area behind the ear of each pig.

Primary vaccination:
First vaccination: one dose 5 weeks before the expected date of farrowing.
Second vaccination: one dose 2 weeks before the expected date of farrowing.

Revaccination (before each subsequent farrowing):
one dose 2 weeks before the expected date of farrowing.

9. ADVICE ON CORRECT ADMINISTRATION

Preparation of the vaccine:
1. To reconstitute the vaccine, use an appropriately sized sterile syringe to withdraw approximately 5 ml of the suspension and transfer it into the vial containing the lyophilisate.

2. Shake gently until the lyophilisate is completely dispersed in the suspension.

3. Then withdraw all the contents of the lyophilisate vial into the same syringe and transfer them back into the suspension vial.

4. Shake well until thoroughly mixed.

5. Withdraw approximately 5 ml of the reconstituted vaccine suspension and transfer it into the lyophilisate vial. Shake the vial. Then withdraw the contents and transfer them back into the vaccine suspension vial.

The vaccine is ready to use.
The reconstituted vaccine is a yellowish brown to reddish brown suspension.

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).
Protect from light.
Do not freeze.

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

Shelf life after reconstitution according to directions: 8 hours. Until use the reconstituted vaccine should been stored at 2-8 °C. After removal of the reconstituted vaccine from storage at 2-8 °C, the vaccine should be used immediately.

12. SPECIAL WARNINGS

Special warnings for each target species:
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:
None.

Pregnancy and lactation:
Can be used during pregnancy.

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):
Not applicable.

Incompatibilities:
Do not mix with any other veterinary medicinal product, except the suspension supplied for use with the veterinary medicinal product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2022

15. OTHER INFORMATION

Pack sizes:
10 doses: Cardboard box containing 1 glass vial of lyophilisate and 1 glass vial (20 ml) of suspension
10 doses: Cardboard box containing 1 glass vial of lyophilisate and 1 PET vial (20 ml) of suspension

25 doses: Cardboard box containing 1 glass vial of lyophilisate and 1 glass vial (50 ml) of suspension.
25 doses: Cardboard box containing 1 glass vial of lyophilisate and 1 PET vial (50 ml) of suspension

Not all pack sizes may be marketed.

Immunological properties
The active immunisation of pregnant sows and gilts induces the formation of antibodies against the alpha, beta1 and beta2 toxins of *C. perfringens* types A/C and against the *E. coli* fimbrial adhesins F4ab, F4ac, F5 and F6. The piglets are then passively immunised by the uptake of colostrum that contains those specific antibodies.

Efficacy of the vaccine has been demonstrated upon intraperitoneal challenge with a combination of alpha and beta2 toxins from *C. perfringens* type A. This toxin pattern is representative for the majority of *C. perfringens* type A isolates in the field associated with neonatal enteritis. Both toxins have been proposed to play a role in the pathogenesis.

Approved 19 October 2022