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 suspension for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

One dose (2 ml) contains:
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

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}
Once opened use 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 15052/5031

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial 10 doses
Vial 25 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enteroporc COLI suspension for injection for pigs

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

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Once opened use immediately.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Enteroporc COLI 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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enteroporc COLI suspension for injection for pigs

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENT

One dose (2 ml) contains:

Active substances:
Inactivated fimbrial adhesins of *Escherichia coli*:

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

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

Adjuvant:
Aluminium (as hydroxide) 2.0 mg/ml

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.

Onset of immunity (after uptake of colostrum): within 12 hours after birth
Duration of immunity (after uptake of colostrum): first 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 days 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 (2ml) of vaccine into the 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

Shake the vaccine well before use.

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 the expiry date which is stated on the label and carton.

Shelf life after first opening the container: Use 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:
Not applicable.

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.

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 Immunological properties

The active immunisation of pregnant sows and gilts induces the formation of antibodies against the *E. coli* fimbrial adhesins F4ab, F4ac, F5 and F6. Piglets are then passively immunised by the uptake of colostrum that contains those specific antibodies.

Pack sizes:
Cardboard box containing 1 vial (glass or PET) with 10 doses of suspension
Cardboard box containing 1 vial (glass or PET) with 25 doses of suspension

Not all pack sizes may be marketed.

Approved 20 October 2022