SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Adjuvant:

Aluminium (as hydroxide)	2.0 mg/ml

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and suspension for suspension for injection.

Beige to brown lyophilisate.
Yellowish suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs (pregnant sows and gilts).

4.2 Indications for use, specifying the target species

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

- Clinical signs (severe diarrhoea) and mortality caused by *Escherichia coli* strains expressing the fimbrial 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 necrotising 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 (after uptake of colostrum):
E. coli F4ab, F4ac, F5, F6: first days of life
C. perfringens type A: 14 days of life
C. perfringens types C: 21 days of life

4.3 Contraindications

None.

4.4 Special warnings for each target species

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

None.

4.6 Adverse reactions (frequency and seriousness)

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).

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy.

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.

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

Vaccination scheme:

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.

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 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.

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

Not applicable.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Suidae, inactivated bacterial vaccines.
ATC vet code: QI09AB08.

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 and C and against *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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:
Sucrose

Suspension:
Aluminium hydroxide
Sodium chloride
Disodium hydrogen phosphate dihydrate
Potassium dihydrogen phosphate
Water for injection

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

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

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Lyophilisate:
10 ml glass (type I) vials containing 10 or 25 doses

Suspension:
25 ml polyethylene terephthalate (PET) or glass (type I) vials containing 10 doses (20 ml)
50 ml PET or glass (type II) vials containing 25 doses (50 ml)
50 ml low density polyethylene (LDPE) bottles containing 25 doses (50 ml)

The vials are closed with bromobutyl rubber stoppers and sealed with aluminium crimp caps.

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

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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
Explorer House
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Wycombe Lane
Wooburn Green
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Buckinghamshire
HP10 0HH
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 15052/5002

9. DATE OF FIRST AUTHORISATION

09 December 2020

10. DATE OF REVISION OF THE TEXT

February 2025

Approved 04 March 2025
Gavin Hall