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 2 ml dose contains:

Active substances:

Lyophilisate:

Clostridium perfringens, type A, alpha toxoid	≥125 rU/ml*
Clostridium perfringens, type A, beta2 toxoid	≥794 rU/ml*
Clostridium perfringens, type C, beta1 toxoid	≥ 3,354 rU/ml*

Suspension:

Escherichia coli, fimbrial adhesin F4ab	≥ 23 rU/ml*
Escherichia coli, fimbrial adhesin F4ac	≥ 19 rU/ml*
Escherichia coli, fimbrial adhesin F5	≥ 13 rU/ml*
Escherichia coli, fimbrial adhesin 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

Excipients:

Qualitative composition of excipients and other constituents
Lyophilisate:
Sucrose
Suspension:
Aluminium hydroxide
Sodium chloride
Disodium hydrogen phosphate dihydrate
Potassium dihydrogen phosphate
Water for injections

Beige to brown lyophilisate.
Yellowish suspension.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (pregnant sows and gilts).

3.2 Indications for use for each 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: 2 weeks of life.
C. perfringens type C: 3 weeks of life.

3.3 Contraindications

None.

3.4 Special warnings

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:

Not applicable.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Target species: Pigs (pregnant sows and gilts):

Very common (>1 animal / 10 animals treated):	Hyperthermia[1] Injection site swelling[2], injection site reddening[2]
Common (1 to 10 animals / 100 animals treated):	Depression[3]

[1] transient (mean 0.5 °C, in individual pigs up to 2 °C) on the day of vaccination which returns to normal within 24 hours
[2] transient, (mean 2.8 cm, in individual pigs up to 8 cm), disappearing without treatment within 7 days
[3] slight on day of vaccination

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:

Can be used during pregnancy.

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.

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.

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

Not applicable.

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: QI09AB08

Immunologicals for Suidae, inactivated bacterial vaccines.

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 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.

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

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.

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 NUMBER

Vm 15052/5002

8. DATE OF FIRST AUTHORISATION

09 December 2020

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

January 2026

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: 28 April 2026