SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enteroporc COLI suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 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 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

Suspension for injection.

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.

Onset of immunity (after uptake of colostrum): within 12 hours after birth
Duration of immunity (after uptake of colostrum): first 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

Not applicable.

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 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).

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.

Shake the vaccine well before use.

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, *Escherichia*.
ATC vet code: QI09AB02.

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 21 months

Shelf life after first opening the immediate packaging: Use 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

25 ml PET or glass type I vials containing 10 doses.
50 ml PET or glass type II vials containing 25 doses.

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

Pack sizes:
Cardboard box containing 1 PET vial with 10 doses of suspension.
Cardboard box containing 1 PET vial with 25 doses of suspension.
Cardboard box containing 1 glass vial with 10 doses of suspension.
Cardboard box containing 1 glass vial with 25 doses 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
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
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8. MARKETING AUTHORISATION NUMBER

Vm 15052/5031

9. DATE OF FIRST AUTHORISATION

27 January 2021

10. DATE OF REVISION OF THE TEXT

October 2022

Approved 20 October 2022