ANNEX I

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 Santé Animale
10 av. de La Ballastière
33500 Libourne
France

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/20/268/001-004

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 06.01.2021

10. DATE OF REVISION OF THE TEXT

{MM/YYYY}

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

A. MANUFACTURERS OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

A. MANUFACTURERS OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturers of the biological active substance

IDT Biologika GmbH
Am Pharmapark
06861 Dessau-Rosslau
Germany

Name and address of the manufacturer responsible for batch release

IDT Biologika GmbH
Am Pharmapark
06861 Dessau-Rosslau
Germany

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

The active substance being a principle of biological origin intended to produce passive immunity is not within the scope of Regulation (EC) No 470/2009.

The excipients (including adjuvants) listed in section 6.1 of the SPC are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

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 Santé Animale
10 av. de La Ballastière
33500 Libourne
France

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/20/268/001
EU/2/20/268/002
EU/2/20/268/003
EU/2/20/268/004

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 Santé Animale
10 av. de La Ballastière
33500 Libourne
France

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

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

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.