SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Coliprotec F4/F18 lyophilisate for oral suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of vaccine contains:

Active substances:
Live non-pathogenic *Escherichia coli* O8:K87* (F4ac):.....1.3x10^8 to 9.0x10^8 CFU**
Live non-pathogenic *Escherichia coli* O141:K94* (F18ac): .....2.8x10^8 to 3.0x10^9 CFU**

*not attenuated
**CFU – colony forming units

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate for oral suspension.
White or whitish powder.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs.

4.2 Indications for use, specifying the target species

For active immunisation of pigs from 18 days of age against enterotoxigenic F4-positive and F18-positive *Escherichia coli* in order to:

- reduce the incidence of moderate to severe post-weaning *E. coli* diarrhoea (PWD) in infected pigs;
- reduce the faecal shedding of enterotoxigenic F4-positive and F18-positive *E. coli* from infected pigs.

Onset of immunity: 1 week
Duration of immunity: 3 weeks

4.3 Contraindications

None.

4.4 Special warnings for each target species

It is not recommended to vaccinate animals undergoing immunosuppressive treatment or to vaccinate animals undergoing antibacterial treatment effective against *E. coli*.
Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals
The vaccine strains may be excreted by vaccinated piglets for at least 14 days following vaccination. The vaccine strains readily spread to other pigs in contact with vaccinated pigs. Unvaccinated pigs in contact with vaccinated pigs will harbour and shed the vaccine strains similarly to vaccinated pigs. During this time, the contact of immunosuppressed pigs with vaccinated pigs should be avoided.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Personal protective equipment consisting of protective disposable gloves and safety glasses should be worn when handling the veterinary medicinal product.

In case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the physician. In case of spillage onto skin, rinse with water and seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment
Not applicable.

Other precautions
Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Pigs:
None known.

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 also section 16 of the package leaflet for contact details.

4.7 Use during pregnancy, lactation or lay

Pregnancy:
The use is not recommended 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 Amount(s) to be administered and administration route

Oral use.
Vaccination schedule: administer a single dose orally from 18 days of age.

All materials used in preparing and administering the vaccine must be free of antimicrobials, detergent or disinfectant residues to prevent inactivation.

The reconstituted vaccine is a transparent to opaque white-yellowish suspension depending on the volume of water used for dilution.

Vaccination by drench application:

- 50-dose presentation: Reconstitute the lyophilisate by adding 10 ml of water to the vial. Shake well and transfer the suspension into a graduated container, mix again with water to complete to a total volume of 100 ml. Shake well and use within 4 hours. Administer a single 2 ml dose orally to pigs, irrespective of body weight.

- 200-dose presentation: Reconstitute the lyophilisate by adding 20 ml of water to the vial. Shake well and transfer the suspension into a graduated container, mix again with water to complete to a total volume of 400 ml. Shake well and use within 4 hours. Administer a single 2 ml dose orally to pigs, irrespective of body weight.

Vaccination via the drinking water system:
The drinking water systems have to be cleaned and intensively rinsed with untreated water to avoid any residues of antimicrobials, detergents or disinfectants.

Withhold drinking water supply for 1 to 2 hours prior to the planned vaccination to stimulate drinking of the vaccine suspension.

Reconstitute the lyophilisate by adding 10 ml (50-dose presentation) or 20 ml (200-dose presentation) of water to the vial. Shake well.

The final suspension containing the vaccine should be consumed within 4 hours after preparation. Provide enough space so that all pigs can drink the required amount. The actual amount of water consumed may however vary considerably depending on several factors. Therefore, it is recommended to assess the

actual water intake during a 4-hour time period the day before vaccination. Alternatively, refer to the following table:

Body weight (kg)	Water consumption (litres) in a 4-hour time period		
	1 pig	50 pigs	200 pigs
Up to 4.5	0.11 litres	5.5 litres	22 litres
4.6 to 6.8	0.17 litres	8.5 litres	34 litres
6.9 to 9.0	0.23 litres	11.5 litres	46 litres

- For administration using bowls or tanks, dilute the reconstituted vaccine in the volume of water that the pigs will drink during a 4-hour time period.
- For administration through water lines using a dosing pump (proportioner), dilute the reconstituted vaccine in the needed volume of the dosing pump stock solution. The volume of stock solution is calculated using the volume of water that the pigs will drink during a 4-hour time period multiplied by the dosing pump rate (in decimal). As an example, for a 4-hour consumption of 22 litres and a dosing pump rate of 1%, the volume of the stock solution should be 22 litres x 0.01 = 220 ml.

In case of concerns about the presence of disinfectant residues in the drinking water, such as chlorine, it is recommended to add skimmed milk powder as a stabiliser into the drinking water prior to adding the vaccine. The final concentration of the skimmed milk powder should be 5 g/litre.

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

A rectal temperature up to 41.2 °C may occur in individual animals within the first 24 hours after administration of a 10-fold overdose.

4.11 Withdrawal period(s)

Zero days.

5. PHARMACOLOGICAL IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Suidae; live bacterial vaccine, escherichia

ATCvet code: QI09AE03.

To stimulate active immunity against enterotoxigenic F4-positive and F18-positive *E. coli* in pigs.

The vaccine induces an intestinal immunity and a serological response against F4-positive and F18-positive *E. coli* in pigs. The vaccine confers cross protection against F18ab-positive *E. coli,* as demonstrated by challenge for both the 7-day onset of immunity and the 21-day duration of immunity. Antibodies triggered by the vaccine provide cross-reactivity against F4ab and F4ad-positive *E. coli* strains.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dextran 40,000
Sucrose
Monosodium glutamate
Purified water

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: 2 years.
Shelf life after reconstitution and dilution according to directions: 4 hours.

6.4 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Protect from light.

6.5 Nature and composition of immediate packaging

Type I glass vial of 11 ml containing 50 doses and type II glass vial of 50 ml containing 200 doses with a chlorobutyl rubber stopper sealed with an aluminium cap.

Cardboard box of one vial of 50 or 200 doses.
Cardboard box of four vials of 50 doses.

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

Medicines should not be disposed of via wastewater.
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

Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 00879/5000

9. DATE OF FIRST AUTHORISATION

09 January 2017

10. DATE OF REVISION OF THE TEXT

July 2024

PROHIBITION OF SALE, SUPPLY AND/OR USE
Not applicable

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

Gavin Hall

Approved 20 July 2024