

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**  
**CARDBOARD BOX**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Coliprotec F4/F18 lyophilisate for oral suspension

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Live non-pathogenic <i>E. coli</i> O8:K87 (F4ac):	1.3x10 <sup>8</sup> to 9.0x10 <sup>8</sup> CFU/dose
Live non-pathogenic <i>E. coli</i> O141:K94 (F18ac):	2.8x10 <sup>8</sup> to 3.0x10 <sup>9</sup> CFU/dose

**3. PACKAGE SIZE**

1 x 50 doses  
4 x 50 doses  
1 x 200 doses

**4. TARGET SPECIES**

Pigs

**5. INDICATION(S)**

**6. ROUTES OF ADMINISTRATION**

Oral use

**7. WITHDRAWAL PERIODS**

Withdrawal period: zero days

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once reconstituted use within 4 hours.

**9. SPECIAL STORAGE PRECAUTIONS**

Store and transport refrigerated.  
Protect from light.

**10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.

**11. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**13. NAME OF THE MARKETING AUTHORISATION HOLDER**

Elanco Europe Ltd.

**14. MARKETING AUTHORISATION NUMBERS**

Vm 00879/5000

**15. BATCH NUMBER**

Lot {number}

**16. SPECIAL WARNING(S), IF NECESSARY**

**17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: read package leaflet.

**18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

POM-V

Veterinary medicinal product subject to prescription

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING  
UNITS**  
**Vials (50 or 200 doses)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Coliprotec F4/F18

**2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE  
SUBSTANCES**

50 /200 doses live *E. coli* O8:K87 (F4ac) and live *E. coli* O141:K94 (F18ac)

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

Once reconstituted use within 4 hours.

**5. ROUTE(S) OF ADMINISTRATION**

Oral use

**6. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

## **PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Coliprotec F4/F18 lyophilisate for oral suspension

### **2. COMPOSITION**

Each dose of vaccine contains:

Live non-pathogenic *E. coli* O8:K87 (F4ac):.....1.3x10<sup>8</sup> to 9.0x10<sup>8</sup> CFU\*

Live non-pathogenic *E. coli* O141:K94 (F18ac):.....2.8x10<sup>8</sup> to 3.0x10<sup>9</sup> CFU\*

\*not attenuated

\*CFU – colony forming units

White or whitish powder.

### **3. TARGET SPECIES**

Pigs

### **4. INDICATIONS FOR USE**

For active immunisation of pigs from 18 days of age against enterotoxigenic F4-positive and F18-positive *E. 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 after vaccination

Duration of immunity: 3 weeks after vaccination

### **5. CONTRAINDICATIONS**

None

### **6. SPECIAL WARNINGS**

#### Special warnings:

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.

#### Special precautions for safe use in the target species:

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.

Pregnancy:

The use is not recommended 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:

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.

Major incompatibilities:

Do not mix with any other veterinary medicinal product.

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## **7. ADVERSE EVENTS**

**Pigs:**

No adverse events have been observed.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

E-mail: [adverse.events@vmd.gov.uk](mailto:adverse.events@vmd.gov.uk)

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

## 8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Oral use.

Administer a single dose of vaccine from 18 days of age.

## 9. ADVICE ON CORRECT ADMINISTRATION

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

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

The reconstituted vaccine is 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.

## 10. WITHDRAWAL PERIODS

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 use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

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

## 12. SPECIAL PRECAUTIONS FOR DISPOSAL

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.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

### 13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription

### 14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 00879/5000

Pack sizes:

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.

### 15. PID LINK (Do not print heading)

*[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]*

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

### 16. CONTACT DETAILS

Marketing authorisation holder and contact details to report suspected adverse reactions:

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

Tel: +44 3308221732

[PV.GBR@elancoah.com](mailto:PV.GBR@elancoah.com)

Manufacturers responsible for batch release:

Lohmann Animal Health GmbH  
Heinz-Lohmann-Str. 4  
27472 Cuxhaven  
GERMANY

### 17. OTHER INFORMATION

Immunological properties:

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.

POM-V

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*Gavin Hall*

Approved 20 July 2024