PARTICULARS TO APPEAR ON THE OUTER PACKAGE (CARDBOARD BOX)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Entericolix emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

One dose (2 ml) contains:

Escherichia coli, strain P4, fimbrial adhesin F6, Inactivated	≥ 1 RP *
Escherichia coli, strain P5, fimbrial adhesin F18ab, Inactivated	≥ 1 RP *
Escherichia coli, strain P6, fimbrial adhesin F4ac Inactivated	≥ 1 RP *
Escherichia coli, strain P9, fimbrial adhesin F18ac, Inactivated	≥ 1 RP *
Escherichia coli, strain P10, fimbrial adhesin F5 and F41, Inactivated	≥ 1 RP *
Clostridium perfringens, type C, strain CZV13, beta toxoid	≥ 10 IU ** of β antitoxin/ml of rabbit serum

* RP: Relative potency for each antigen according to a reference vaccine with satisfactory result in the immunogenicity test (Ph. Eur. Monograph 0962).
** IU: International units of beta toxin (Ph. Eur. Monograph 0363).

3. PACKAGE SIZE

50 ml (25 doses)

4. TARGET SPECIES

Pig (sow and gilt for reproduction)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: zero days

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 10 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
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

Marketing Authorisation Holder: {CZV company logo}
Local Representative: {Boehringer Ingelheim company logo}
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14. MARKETING AUTHORISATION NUMBERS

Vm 30824/4003

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS (HDPE-BOTTLES OF 50 ML (25 DOSES))

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Entericolix

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

One dose (2 ml) contains:

Inactivated *E. coli* strains expressing the adhesins F6 (P987), F18ab and F18ac, F4ac (K88ac), F5 (K99) and F41: ≥ 1 RP

C. perfringens, type C, beta toxoid: ≥ 10 IU

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

<Exp. {mm/yyyy}>

Once broached use within 10 hours.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Entericolix, emulsion for injection for pig.

2. Composition

One dose (2 ml) contains:

Active substances:

Escherichia coli, strain P4, fimbrial adhesin F6, Inactivated	≥ 1 RP *
Escherichia coli, strain P5, fimbrial adhesin F18ab, Inactivated	≥ 1 RP *
Escherichia coli, strain P6, fimbrial adhesin F4ac Inactivated	≥ 1 RP *
Escherichia coli, strain P9, fimbrial adhesin F18ac, Inactivated	≥ 1 RP *
Escherichia coli, strain P10, fimbrial adhesin F5 and F41, Inactivated	≥ 1 RP *
Clostridium perfringens, type C, strain CZV13, beta toxoid	≥ 10 IU ** of β antitoxin/ml of rabbit serum

* RP: Relative potency for each antigen according to a reference vaccine with satisfactory result in the immunogenicity test (Ph. Eur. Monograph 0962).
** IU: International units of beta toxin (Ph. Eur. Monograph 0363).

Adjuvants:

Light mineral oil	0.760 ml
Montanide 103	0.0425 ml
Sorbitan oleate	0.0425 ml

Excipients:

Thiomersal	0.2 mg

Milky white homogenous emulsion.

3. Target species

Pig (sow and gilt for reproduction).

4. Indications for use

Vaccination of sows and gilts for the passive immunization of piglets against colibacillosis caused by enteropathogenic and enterotoxigenic *E. coli* strains expressing F4ac, F5, F6, F18ac and F41 adhesins, against oedema disease caused by *E. coli* strain expressing F18ab adhesin and against necrotic enteritis caused by *C. perfringens* type C.

Neonatal piglets
- The vaccine reduces mortality and clinical signs (severe diarrhoea) due to colibacillosis.
- The vaccine reduces mortality and clinical signs due to necrotic enteritis caused by *C. perfringens* type C.

Weaned piglets
- The vaccine reduces mortality and clinical signs due to oedema disease.
- The vaccine reduces clinical signs (severe diarrhoea) of colibacillosis.
- The vaccine reduces clinical signs of chronic enteritis due to *C. perfringens* type C.

Duration of immunity
- 21 days for infections caused by F4ac, F18ac (colibacillosis) and *C. perfringens* type C (necrotic enteritis).
- 21 days for antibodies against F5, F6 and F41, however the protective efficacy of the antibody levels was not established.
- 28 days for infections caused by F18ab (oedema disease).

5. Contraindications

Do not use in cases of hypersensitivity to the active substances, to the adjuvants or to any of the excipients.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

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:

To the user:
This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this veterinary medicinal product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

Special precautions for the protection of the environment:
Not applicable.

Pregnancy:
Can be used during pregnancy.
The vaccine should not be given in the 4-week period before the expected farrowing date.

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:
After administration of a 2-fold recommended dose of the vaccine, a slightly higher transient temperature increase may be observed compared to that after a single vaccine dose (e.g. temperature increase of up to 2.5 ºC after a double dose).

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Pigs:

Very common (>1 animal / 10 animals treated):
Hyperthermia[1]
Common (1 to 10 animals / 100 animals treated):
Apathy[2]
Rare (1 to 10 animals / 10,000 animals treated):
Injection site swelling, injection site reddening[3]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Anaphylactic-type reaction (severe allergic reaction)[4]

[1] Transient, maximum 2 ºC, between 4 – 24 hours after vaccination. Temperatures return to normal values within 24 – 48 hours.
[2] Between 1- and 2-days post-vaccination, uncommonly may last for up to 7 days after vaccination.

[3] With a maximum diameter of 3 cm and a maximum of 10 days of duration.
[4] May be fatal.

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 or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

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

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Intramuscular use.

Doses ***Sows and gilts***: 2 ml.

Vaccination schedule

Pregnant sows: The initial course consists of two doses. Administer one dose 7 weeks before farrowing followed by a second dose 4 weeks before farrowing. Revaccinate with a single dose 4 weeks before farrowing in subsequent gestating periods.

9. Advice on correct administration

Before use, allow the vaccine to reach room temperature and shake the bottle vigorously. Inoculate the corresponding dose by deep intramuscular injection in the neck muscles. It is very important to use needles of appropriate length according to the weight of the animal.
It is recommended that the second dose should be given preferably on the alternate side.

Shake vigorously before use and at intervals during use.
Avoid introduction of contamination during use.

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).
Do not freeze.
Protect from light.
Shelf life after first opening the immediate packaging: 10 hours.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and label after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

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 applicable national collection systems. 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 30824/4003

Cardboard box with 1 multi-dose high-density polyethylene (HDPE) bottle of 50 ml (25 doses) with a perforable nitrile rubber stopper and aluminium seal

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.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:
CZ Vaccines S.A.U.
A Relva s/n – Torneiros
36410 O Porriño
Pontevedra
Spain

Local representatives and contact details to report suspected adverse reactions:
Boehringer Ingelheim Animal Health UK Ltd.
Bracknell, RG12 8YS, UK

Tel: +44 (0) 01344 746957

17. Other information

ATC vet code. QI09AB08

The vaccine contains inactivated strains of Escherichia coli expressing the adhesins F4ac, F5, F6, F18ab, F18ac and F41 which cause neonatal enterotoxicosis in piglets, as well as β-enterotoxin from Clostridium perfringens type C. The vaccine is formulated with an oily adjuvant. In sows and gilts, the vaccine induces the specific seroconversion of vaccinated animals; piglets are passively immunised by intake of colostrum containing Escherichia coli adhesin-specific and Clostridium perfringens anti-enterotoxin antibodies.

POM-V

Gavin Hall
Approved: 02 April 2025