SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Entericolix, emulsion for injection for pig

2. QUALITATIVE AND QUANTITATIVE 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:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Disodium phosphate, anhydrous	
Formaldehyde	
Polysorbate 80	
Potassium dihydrogen phosphate	
Sodium chloride	
Thiomersal	0.2 mg
Water for injections	

Milky white homogenous emulsion

3. CLINICAL INFORMATION

3.1 Target species

Pig (sow and gilt for reproduction).

3.2 Indications for use for each target species

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).

3.3 Contraindications

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

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

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.

3.6 Adverse events

Pigs:

Very common (>1 animal / 10 animals treated):	Hyperthermia1
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[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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

3.8 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.

3.9 Administration routes and dosage

Intramuscular use.

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

Doses
Sows and gilts: 2 ml.
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.

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 gestation periods.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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).

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging:10 hours

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).>
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

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.

5.5 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 or household waste.

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

CZ Vaccines S.A.U.

7. MARKETING AUTHORISATION NUMBER

Vm 30824/4003

8. DATE OF FIRST AUTHORISATION

27 January 2016

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

December 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Gavin Hall
Approved: 02 April 2025