[Version 8.1, 01/2017]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Entericolix, emulsion for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose (2ml) of the inactivated vaccine contains:

Active substances:

Escherichia coli strain P4 (F6 adhesins),	≥ 1 RP *
Escherichia coli strain P5 (F18ab adhesins),	≥ 1 RP *
Escherichia coli strain P6 (F4ac adhesins),	≥ 1 RP *
Escherichia coli strain P9 (F18ac adhesins),	≥ 1 RP *
Escherichia coli strain P10 (F5 + F41 adhesins),	≥ 1 RP *
beta toxoid of *Clostridium perfringens* type C (CZV13)	≥ 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)

Adjuvant:

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

Excipients:

Thiomersal	0.2 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection
Milky white homogenous emulsion

4. CLINICAL PARTICULARS

4.1 Target species

Pigs (sows and gilts for reproduction).

4.2 Indications for use, specifying the 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 *Clostridium 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)

4.3 Contraindications

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

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

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 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 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.

4.6 Adverse reactions (frequency and seriousness)

A transient increase in body temperature (maximum 2ºC) can be observed between 4–24 hours after vaccination, this event is very common. Temperatures return to normal values within 24–48 hours.

The vaccine can produce short term apathy between 1 and 2 days post-vaccination, this event is common. Apathy may last for up to 7 days after vaccination, however this event is uncommon.

Injection site reactions (swelling and reddening) occurred rarely, with a maximum of 3 cm of diameter and a maximum of 10 days of duration.

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.

The vaccine should not be given in the 4 week period before the expected farrowing date.

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.

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.

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

After administration of a double vaccine dose, 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).

4.11 Withdrawal period

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated bacterial vaccines against *Escherichia coli* and *Clostridium perfringens*.

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium phosphate, anhydrous
Formaldehyde
Light mineral oil
Montanide 103
Thiomersal
Polysorbate 80
Potassium dihydrogen phosphate
Sodium chloride
Sorbitan oleate
Water for injections

6.2 Major incompatibilities

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

6.3 Shelf life

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

6.4 Special precautions for storage

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

6.5 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.

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 products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

CZ Veterinaria, S.A.
La Relva s/n- Torneiros
36410 Porriño (Spain)

8. MARKETING AUTHORISATION NUMBER

To be completed nationally.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27/01/2016
Date of last renewal:

10 DATE OF REVISION OF THE TEXT

To be completed nationally.

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable