

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Entericolix, emulsion for injection for pigs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One dose (2ml) of the vaccine contains:

-Inactivated E. coli strains expressing the adhesins F6 (P987), F18ab and F18 ac, F4ac (K88ac), F5 (K99) and F41 ≥ 1 RP
-beta toxoid of *C. perfringens* type C ≥ 27.78 IU
Adjuvant: Light mineral oil (0.760 ml), Montanide 103 (0.0425 ml), Sorbitan oleate (0.0425 ml);
Preservative: Thiomersal (0.2 mg).

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

50 ml (25 doses)

5. TARGET SPECIES

Pigs

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Deep IM use

8. WITHDRAWAL PERIOD

Withdrawal period: zero days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
Accidental self-injection is dangerous.

10. EXPIRY DATE

EXP {month/year}

Once broached use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated. Do not freeze. Protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

17. MANUFACTURER’S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottles of 50 ml (25 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Entericolix, emulsion for injection for pigs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

One dose (2 ml) contains:

Inactivated *E. coli* strains expressing F6 (P987), F18ab and F18ac, F4ac (K88ac), F5 (K99), F41 and beta toxoid of *C. perfringens* type C.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 ml (25 doses)

4. ROUTE(S) OF ADMINISTRATION

Deep IM use

5. WITHDRAWAL PERIOD

Withdrawal period: zero days.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}

Once broached use within 10 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.