ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

10 doses, 20 ml solvent
25 doses, 50 ml solvent

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enteroporc AC
Lyophilisate and solvent for suspension for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

One dose (2 ml of the reconstituted vaccine) contains:
Clostridium perfringens type A/C toxoids:

alpha toxoid	min. 125 rU/ml*
beta1 toxoid	min. 3354 rU/ml*
beta2 toxoid	min. 770 rU/ml*

*toxoid content in relative units per ml, determined in ELISA against an internal standard

Montanide Gel	37.4 – 51.5 mmol/l titratable acrylate units
Thiomersal	0.085 – 0.115 mg/ml

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection

4. PACKAGE SIZE

10 doses, 20 ml solvent
25 doses, 50 ml solvent

5. TARGET SPECIES

Pigs (pregnant sows and gilts)

6. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Intramuscular use.

7. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

8. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

9. EXPIRY DATE

EXP {month/year}
Once reconstituted, use within 24 hours.

10. SPECIAL STORAGE CONDITIONS

Store below 25 °C. Do not freeze. Protect from light.

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

Disposal: read package leaflet.

12. 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.

13. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

14. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

IDT Biologika GmbH
Am Pharmapark
06861 Dessau-Rosslau
Germany

15. MARKETING AUTHORISATION NUMBER(S)

Vm 26750/3000

16. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

10 doses
25 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enteroporc AC
Lyophilisate and solvent for suspension for injection for pigs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Clostridium perfringens type A/C toxoids

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

10 doses
25 doses

4. ROUTE(S) OF ADMINISTRATION

Intramuscular use.

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Once reconstituted, use within 24 hours.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING (LABEL) OF THE DILUENT
(normal sized bottles)

20 ml solvent
50 ml solvent

1. NAME OF THE DILUENT

Solvent for resuspension for lyophilised ENTEROPORC vaccines

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

20 ml
50 ml

3. ROUTE(S) OF ADMINISTRATION

Read package leaflet before use.

4. STORAGE CONDITIONS

Store below 25 °C. Do not freeze. Protect from light.

5. BATCH NUMBER

Lot (number)

6. EXPIRY DATE

EXP {month/year}

7. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

IDT Biologika GmbH

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Enteroporc AC
Lyophilisate and solvent for suspension for injection for pigs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:
IDT Biologika GmbH
Am Pharmapark
06861 Dessau-Rosslau
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enteroporc AC
Lyophilisate and solvent for suspension for injection for pigs

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

One dose (2 ml of the reconstituted vaccine) contains:
Clostridium perfringens type A/C toxoids:

alpha toxoid	min. 125 rU/ml*
beta1 toxoid	min. 3354 rU/ml*
beta2 toxoid	min. 770 rU/ml*
Montanide Gel	37.4 – 51.5 mmol/l titratable acrylate units
Thiomersal	0.085 – 0.115 mg/ml

*toxoid content in relative units per ml, determined in ELISA against an internal standard

Lyophilisate and solvent for suspension for injection.
Beige to brown lyophilisate.

4. INDICATION(S)

For the passive immunisation of progeny by active immunisation of sows and gilts to reduce mortality and clinical signs during the first days of life caused by *Clostridium perfringens* type A associated enteritis and necrotising enteritis induced by *Clostridium perfringens* type C.

Onset of immunity:
This protection was proven in a challenge test with toxins on suckling piglets on the first day of life.

Duration of immunity:
Serological data show that neutralising antibodies are present up to the 2nd week after birth. The presence of neutralising antibodies has been shown to correlate to protection.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Slight increases in body temperature (in individual cases a maximum increase of 2.4 °C) on the day of vaccination are very common.
Local reactions (flat swellings, with a maximum diameter of 10 cm in isolated cases) at the injection site are very common, but subside without treatment within 14 days.

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).

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 inform your veterinary surgeon.

Alternatively you can report via your national reporting system.

7. TARGET SPECIES

Pigs (pregnant sows and gilts)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Intramuscular injection of 1 dose (2 ml) per pig in the neck in the area behind the ear.

<u>Primary vaccination of pregnant sows before farrowing:</u>
Administer a single dose 5 weeks and 2 weeks before the expected date of farrowing.

<u>Primary vaccination of gilts before insemination:</u>
Administer a single dose 7 weeks and 4 weeks before insemination, and 2 weeks before the expected date of farrowing.

<u>Revaccination:</u>
Administer a single dose 2 weeks before the expected date of each subsequent farrowing.

9. ADVICE ON CORRECT ADMINISTRATION

If applicable, the solvent is warmed to room temperature prior to reconstitution. To reconstitute the vaccine, transfer ca. 5 ml of the solvent into the small vial containing the lyophilisate by using a syringe. Shake gently to dissolve the vaccine and transfer the dissolved vaccine into the bottle with the solvent. The reconstituted vaccine is used to rinse the lyophilisate bottle using approximately 5 ml. Use sterile syringes and needles.

The vaccine is to be shaken before use. After shaking the vaccine shall be stored upright for ca. 8 - 10 minutes until no more air bubbles are visible in the suspension.

Appearance after reconstitution: amber to brown, slightly opaque liquid.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store below 25 °C. Do not freeze. Protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton.
Shelf life after reconstitution according to directions: 24 hours. Between uses the vaccine should be stored at 2 - 8 °C.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Vaccinate only healthy animals.
Protection of piglets is achieved by colostrum intake. Therefore, care should be taken to ensure that each piglet ingests a sufficient quantity of colostrum.

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 traces of mineral oil as a constituent of Montanide Gel. 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 traces of mineral oil as a constituent of Montanide Gel. 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.

Pregnancy and lactation:

Can be used 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 (symptoms, emergency procedures, antidotes):

After administration of the double dose no other symptoms other than those described in the section “Adverse reactions” were observed.

Incompatibilities:

Do not mix with any other veterinary medicinal product, except solvent supplied for use with the veterinary medicinal product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

June 2022

15. OTHER INFORMATION

Pack sizes:
Cardboard box with 1 bottle of lyophilisate (10 doses) and 1 bottle of solvent (20 ml)
Cardboard box with 5 bottles of lyophilisate (50 doses) and 5 bottles of solvent (5x20 ml)

Cardboard box with 10 bottles of lyophilisate (100 doses) and 10 bottles of solvent (10x20 ml)

Cardboard box with 1 bottle of lyophilisate (25 doses) and 1 bottle of solvent (50 ml)
Cardboard box with 4 bottles of lyophilisate (100 doses) and 4 bottles of solvent (4x50 ml)

Cardboard box with 10 bottles of lyophilisate (250 doses) and 10 bottles of solvent (10x50 ml)
Cardboard box with 20 bottles of lyophilisate (500 doses) and 20 bottles of solvent (20x50 ml)
Cardboard box with 40 bottles of lyophilisate (1000 doses) and 40 bottles of solvent (40x50 ml)

Not all pack sizes may be marketed.

Immunological properties
The active immunisation of pregnant sows and gilts induces the formation of antibodies against the alpha, beta1 and beta2 toxins of *Clostridium perfringens* types A and C.
The uptake of sufficient antibodies at the earliest opportunity, via the colostrum, results in a passive protection of the suckling piglets against the toxic effects of the alpha, beta1 and beta2 toxins of *Clostridium perfringens* types A and C taking into account that the importance of the beta2 toxin has not been clarified conclusively. This protection was proven in a challenge test with toxins on suckling piglets on the first day of life. Serological data show that neutralising antibodies are present up to the 2nd week after birth.

Approved 15 July 2022