SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enteroporc AC
Lyophilisate and solvent for suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Active substances:
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

Adjuvant:

Montanide Gel	37.4 – 51.5 mmol/l titratable acrylate units

Excipients:

Thiomersal	0.085 – 0.115 mg/ml

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Target species

Pigs (pregnant sows and gilts)

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

None.

4.4 Special warnings for each target species

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

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 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.

4.6 Adverse reactions (frequency and seriousness)

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).

4.7 Use during pregnancy and lactation

Can be used during pregnancy.

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

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.

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

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

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

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

No symptoms other than those described in section 4.6 were observed after the administration of a double dose.

4.11 Withdrawal period

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for suidae, inactivated bacterial vaccines (including mycoplasma, toxoid and chlamydia).
ATCvet code: QI09AB12.

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Montanide Gel 01 PR
Thiomersal
Glutaraldehyde
Saccharose
Water for injection

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 24 months
Shelf life after reconstitution according to directions: 24 hours
Between uses the vaccine should be stored at 2 - 8 °C.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Lyophilisate:	Injection vial, 10 ml, glass type I
Solvent:	Injection vial, 25 ml, glass type I
	Injection vial, 50 ml, glass type II

The bottles are closed with a bromobutyl rubber stopper and crimped cap.

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.

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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

IDT Biologika GmbH
Am Pharmapark
06861 Dessau-Rosslau
Germany

8. MARKETING AUTHORISATION NUMBER

Vm 26750/4011

9. DATE OF FIRST AUTHORISATION

21 September 2017

10. DATE OF REVISION OF THE TEXT

September 2017

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