ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ecoporc SHIGA suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 1 ml contains:

Active substance:

Genetically modified recombinant Stx2e antigen: $\geq 3.2 \times 10^6$ ELISA units

Adjuvant:

Aluminium (as hydroxide) max. 3.5 mg

Excipient:

Thiomersal max. 0.115 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
Appearance after shaking: yellowish to brownish, homogenous suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs.

4.2 Indications for use, specifying the target species

Active immunisation of piglets from the age of 4 days, to reduce the mortality and clinical signs of oedema disease caused by Stx2e toxin produced by *E. coli* (STEC).

Onset of immunity: 21 days after vaccination
Duration of immunity: 105 days after vaccination

4.3 Contraindications

Do not use in cases of hypersensitivity to the active substance, to the adjuvant 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

In case of accidental self-injection or ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Commonly very small local reactions such as mild swelling at the injection site (maximum of 5 mm) may be observed, but these reactions are transient and subside within a short time (up to seven days) without treatment.
Commonly a slight rise in body temperature (maximum of 1.7 °C) may occur after injection. However, these reactions subside within a short time (maximum of two days) without treatment.
Clinical signs such as temporary mild behavioural disturbances can uncommonly be observed after application of Ecoporc SHIGA.

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

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Pregnancy and lactation: The use is not recommended during pregnancy and lactation.

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

For intramuscular use. The preferred application site is the neck muscle behind the ear. It is recommended to use a needle appropriate for the age of the piglets (preferred size 21G length 16 mm).

Prior to administration, shake the vaccine carefully.

A single intramuscular injection (1 ml) to pigs from the age of 4 days.

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

Following the administration of a double dose of vaccine no adverse reactions other than those described in section 4.6 have been observed.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for suidae, inactivated bacterial vaccines.
ATC vet code: QI09AB02.

The vaccine consisting of genetically modified recombinant Stx2e stimulates an active immunity against Shiga toxin 2e produced by the causative agent of oedema disease in pigs.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide ($Al(OH)_3$)
Thiomersal
Water for injections
Glutaraldehyde

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: 3 years
Shelf life after first opening the immediate packaging: 24 hours
Between the withdrawals, the vaccine should be stored at 2 °C – 8 °C.

6.4. Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Protect from light.

6.5 Nature and composition of immediate packaging

PET bottle containing 50 ml or 100 ml closed with a bromobutyl rubber stopper and sealed with an aluminium tear-off cap.

Pack sizes:
Cardboard box with 1 PET bottle of 50 doses (50 ml) or 100 doses (100 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

Ceva Santé Animale
10 av. de La Ballastière
33500 Libourne
France

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/13/149/001
EU/2/13/149/002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10/04/2013
Date of latest renewal: 20/03/2018

10. DATE OF REVISION OF THE TEXT

{MM/YYYY}

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substance

IDT Biologika GmbH
Am Pharmapark
06861 Dessau-Rosslau
Germany

Name and address of the manufacturer responsible for batch release

IDT Biologika GmbH
Am Pharmapark
06861 Dessau-Rosslau
Germany

Ceva-Phylaxia Veterinary Biologicals Co. Ltd.
Szállás u. 5.
1107 Budapest
Hungary

The printed package leaflet of the medicinal product must state the name and address of the manufacturer responsible for the release of the concerned batch.

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

The active substance being a principle of biological origin intended to produce active immunity is not within the scope of Regulation (EC) No 470/2009.

The excipients (including adjuvants) listed in section 6.1 of the SPC are allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box (with PET bottle of 50 ml or 100 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ecoporc SHIGA suspension for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

One dose (1 ml) contains:
Genetically modified recombinant Stx2e antigen: $\geq 3.2 \times 10^6$ ELISA units

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

50 ml (50 doses)
100 ml (100 doses)

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use.
Read the package leaflet before use.
Intramuscular use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): zero days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened use within 24 hours (store at 2 °C – 8 °C). Between the withdrawals the vaccine should be stored at (2 °C – 8 °C).

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
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

Ceva Santé Animale
10 av. de La Ballastière
33500 Libourne
France

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/13/149/001 PET bottle of 50 ml
EU/2/13/149/002 PET bottle of 100 ml

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ecoporc SHIGA suspension for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

1 dose (1 ml) contains:
Genetically modified recombinant Stx2e antigen: $\geq 3.2 \times 10^6$ ELISA units

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

100 doses

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use.
Read the package leaflet before use.
IM.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): zero days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Once opened use within 24 hours (store at 2 °C – 8 °C).

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Do not freeze.
Protect from light.

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

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

Ceva Santé Animale
10 av. de La Ballastière
33500 Libourne
France

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/13/149/002 PET bottle of 100 ml

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ecoporc SHIGA suspension for injection for pigs

2. QUANTITY OF THE ACTIVE SUBSTANCE

Genetically modified recombinant Stx2e antigen: $\geq 3.2 \times 10^6$ ELISA units/ml

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

50 doses

4. ROUTE OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s): zero days.

6. BATCH NUMBER

Lot: {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Ecoporc SHIGA 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:

Ceva Santé Animale
10 av. de La Ballastière
33500 Libourne
France

Manufacturer responsible for batch release:

IDT Biologika GmbH
Am Pharmapark
06861 Dessau-Rosslau
Germany

Ceva-Phylaxia Veterinary Biologicals Co. Ltd.
Szállás u. 5.
1107 Budapest
Hungary

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ecoporc SHIGA suspension for injection for pigs

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

Each dose of 1 ml contains:

Active substances:
Genetically modified recombinant Stx2e antigen: $\geq 3.2 \times 10^6$ ELISA units

Adjuvant:
Aluminium (as hydroxide) max. 3.5 mg

Excipient:
Thiomersal max. 0.115 mg

Appearance after shaking: yellowish to brownish, homogenous suspension.

4. INDICATION(S)

Active immunisation of piglets from the age of 4 days, to reduce the mortality and clinical signs of oedema disease caused by Stx2e toxin produced by *E. coli* (STEC).

Onset of immunity: 21 days after vaccination
Duration of immunity: 105 days after vaccination

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substance, to the adjuvant or to any of the excipients.

6. ADVERSE REACTIONS

Commonly very small local reactions such as mild swelling at the injection site (maximum of 5 mm) may be observed, but these reactions are transient and subside within a short time (up to seven days) without treatment.
Commonly a slight rise in body temperature (maximum of 1.7 °C) may occur after injection. But these reactions subside within a short time (maximum of two days) without treatment.
Clinical signs such as temporary mild behavioural disturbances can uncommonly be observed after application of Ecoporc SHIGA.

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.

7. TARGET SPECIES

Pigs.

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

Prior to administration, shake the vaccine carefully.
A single intramuscular injection (1 ml) to pigs from the age of 4 days. The preferred application site is the neck muscle behind the ear.

9. ADVICE ON CORRECT ADMINISTRATION

It is recommended to use a needle appropriate for the age of the piglets (preferred size 21G length 16 mm).

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a refrigerator (2 °C – 8 °C).
Do not freeze.

Protect from light.
Shelf life after first opening the container: 24 hours (store at 2 °C – 8 °C). Between the withdrawals the vaccine should be stored at 2 °C – 8 °C.

Do not use this veterinary medicinal product after the expiry date which is stated on the label or carton.

12. SPECIAL WARNING(S)

Special precautions for use in animals:

Only vaccinate healthy animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

In case of accidental self injection or ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. The use is not recommended during pregnancy and lactation.

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 about using this vaccine before or after any other veterinary medicinal product therefore needs to be made by the responsible veterinarian on a case by case basis.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

Overdose (symptoms, emergency procedures, antidotes):

Following the administration of a double dose of vaccine no adverse reactions other than those described in section 6 have been observed.

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

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

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

15. OTHER INFORMATION

PET bottle containing 50 ml or 100 ml closed with a bromobutyl rubber stopper and sealed with an aluminium tear-off cap.

Pack sizes:
Cardboard box with 1 PET bottle of 50 doses (50 ml) or 100 doses (100 ml).

Not all pack sizes may be marketed.