# 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:**

*Escherichia coli*, recombinant Shiga toxin 2e: $\geq 3.2 \times 10^6$ ELISA units

**Adjuvant:**

Aluminium (as hydroxide) max. 3.5 mg

**Excipients:**

| **Qualitative composition of excipients and other constituents** | **Quantitative composition if that information is essential for proper administration of the veterinary medicinal product** |
|---|---|
| Thiomersal | max 0.115 mg |
| Water for injections | |

Appearance after shaking: yellowish to brownish, homogenous suspension.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Pigs

### 3.2 Indications for use for each 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: 3 weeks after vaccination
Duration of immunity: 15 weeks after vaccination

### 3.3 Contraindications

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

### 3.4 Special warnings

Vaccinate healthy animals only.

## 3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

Special precautions for the protection of the environment:

Not applicable.

## 3.6 Adverse events

Pig:

| | |
|---|---|
| Common<br>(1 to 10 animals / 100 animals treated): | Injection site swelling[1]<br>Elevated temperature[2] |
| Uncommon<br>(1 to 10 animals / 1,000 animals treated): | Behavioural disorder[3] |

[1] Small local reaction (maximum of 5 mm), subsiding within a short time (up to seven days) without treatment.
[2] A slight rise in body temperature (maximum of 1.7 °C), subsiding within a short time (maximum of two days) without treatment.
[3] Temporary mild behavioural disturbances.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

## 3.7 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.

## 3.8 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.

## 3.9 Administration routes and dosage

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.

### 3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Following the administration of a double dose of vaccine no adverse reactions other than those described in section 3.6 have been observed.

### 3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

### 3.12 Withdrawal periods

Zero days.

## 4. IMMUNOLOGICAL INFORMATION

### 4.1 ATCvet code: QI09AB02

Immunologicals for suidae, inactivated bacterial vaccines.

The vaccine consisting of *Escherichia coli*, recombinant Shiga toxin 2estimulates an active immunity against Shiga toxin 2e produced by the causative agent of oedema disease in pigs.

## 5. PHARMACEUTICAL PARTICULARS

### 5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

### 5.2 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.

### 5.3 Special precautions for storage

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

### 5.4 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.

### 5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

## 6. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Santé Animale

## 7. MARKETING AUTHORISATION NUMBER(S)

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

## 8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 10/04/2013

## 9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

DD/MM/YYYY

## 10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

## ANNEX II

## OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

**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:
*Escherichia coli*, recombinant Shiga toxin 2e: $\geq 3.2 \times 10^6$ ELISA units

## 3. PACKAGE SIZE

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

## 4. TARGET SPECIES

Pigs

## 5. INDICATIONS

## 6. ROUTES OF ADMINISTRATION

Intramuscular use.

## 7. WITHDRAWAL PERIODS

Withdrawal period: Zero days

## 8. EXPIRY DATE

EXP: {dd/mm/yyyy}
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).

## 9. SPECIAL STORAGE PRECAUTIONS

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

## 10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

## 11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

## 12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

## 13. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Santé Animale

## 14. MARKETING AUTHORISATION NUMBERS

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

## 15. BATCH NUMBER

Lot: {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**PET Bottle (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:
*Escherichia coli*, recombinant Shiga toxin 2e: $\geq 3.2 \times 10^6$ ELISA units

## 3. TARGET SPECIES

Pigs

## 4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.
Intramuscular use.

## 5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days

## 6. EXPIRY DATE

EXP: {dd/mm/yyyy}
Once opened use within 24 hours (store at 2 °C – 8 °C).

## 7. SPECIAL STORAGE PRECAUTIONS

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

## 8. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Santé Animale

## 9. BATCH NUMBER

Lot: {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**PET Bottle (50 ml)**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ecoporc SHIGA

## 2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE

*Escherichia coli*, recombinant Shiga toxin 2e: ≥ 3.2 x $10^6$ ELISA units/ml

## 3. BATCH NUMBER

Lot: {number}

## 4. EXPIRY DATE

EXP: {dd/mm/yyyy}
Once opened use within 24 hours (store at 2 °C – 8 °C).

**B. PACKAGE LEAFLET**

# PACKAGE LEAFLET

## 1. Name of the veterinary medicinal product

Ecoporc SHIGA suspension for injection for pigs

## 2. Composition

Each dose of 1 ml contains:

**Active substances:**
*Escherichia coli*, recombinant Shiga toxin 2e: $\geq 3.2 \times 10^6$ ELISA units

**Adjuvant:**
Aluminium (as hydroxide) max. 3.5 mg

**Excipient:**
Thiomersal max. 0.115 mg

Appearance after shaking: yellowish to brownish, homogenous suspension.

## 3. Target species

Pigs

## 4. Indications for use

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: 3 weeks after vaccination
Duration of immunity: 15 weeks 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. Special warnings

Special warnings:

Vaccinate healthy animals only.

Special precautions for safe use in the target species:

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.

Special precautions for the protection of the environment:

Not applicable.

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 to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

Overdose:

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

Major incompatibilities:

Do not mix with any other veterinary medicinal product.

## 7. ADVERSE EVENTS

Pig:

| | |
|---|---|
| Common<br>(1 to 10 animals / 100 animals treated): | Injection site swelling[1]<br>Elevated temperature[2] |
| Uncommon<br>(1 to 10 animals / 1,000 animals treated): | Behavioural disorder[3] |

[1] Small local reaction (maximum of 5 mm), subsiding within a short time (up to seven days) without treatment.
[2] A slight rise in body temperature (maximum of 1.7 °C), subsiding within a short time (maximum of two days) without treatment.
[3] Temporary mild behavioural disturbances.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system {national system details}.

## 8. Dosage for each species, routes 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 periods

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 immediate packaging: 24 hours. 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 after EXP.

## 12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

## 13. Classification of veterinary medicinal products

Veterinary medicinal products subject to prescription.

## 14. Marketing authorisation numbers and pack sizes

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

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.

## 15. Date on which the package leaflet was last revised

DD/MM/YYYY

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

## 16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Ceva Santé Animale
10 av. de La Ballastière
33500 Libourne
France
Tel: +800 35 22 11 51 - E-mail: pharmacovigilance@ceva.com

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