

**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 (1 to 10 animals / 100 animals treated):	Injection site swelling <sup>1</sup> Elevated temperature <sup>2</sup>
Uncommon (1 to 10 animals / 1,000 animals treated):	Behavioural disorder <sup>3</sup>

<sup>1</sup> Small local reaction (maximum of 5 mm), subsiding within a short time (up to seven days) without treatment.

<sup>2</sup> A slight rise in body temperature (maximum of 1.7 °C), subsiding within a short time (maximum of two days) without treatment.

<sup>3</sup> 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.

LDPE 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).  
Cardboard box with 1 LDPE 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  
EU/2/13/149/003  
EU/2/13/149/004

**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 \(https://medicines.health.europa.eu/veterinary\)](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 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  
EU/2/13/149/003 LDPE bottle of 50 ml  
EU/2/13/149/004 LDPE bottle of 100 ml

**15. BATCH NUMBER**

Lot: {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE****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****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:  $\geq 3.2 \times 10^6$  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 *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 (1 to 10 animals / 100 animals treated):	Injection site swelling <sup>1</sup> Elevated temperature <sup>2</sup>
Uncommon (1 to 10 animals / 1,000 animals treated):	Behavioural disorder <sup>3</sup>

<sup>1</sup> Small local reaction (maximum of 5 mm), subsiding within a short time (up to seven days) without treatment.

<sup>2</sup> A slight rise in body temperature (maximum of 1.7 °C), subsiding within a short time (maximum of two days) without treatment.

<sup>3</sup> 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 therefrom 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

EU/2/13/149/003 LDPE bottle of 50 ml

EU/2/13/149/004 LDPE 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.

LDPE 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).

Cardboard box with 1 LDPE 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) (<https://medicines.health.europa.eu/veterinary>).

**16. Contact details**

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

Ceva Santé Animale  
8 rue de Logrono  
33500 Libourne  
France  
Tel: +800 35 22 11 51 - E-mail: [pharmacovigilance@ceva.com](mailto: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