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: ≥ 3.2 x 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. {mm/yyyy}

Once opened use within24 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 Animal Health Ltd

14. MARKETING AUTHORISATION NUMBER

Vm 15052/5006

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE Bottle 100ml

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: ≥ 3.2 x 10^6 ELISA units

3. TARGET SPECIES

Pigs

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.
Intramuscular.

5. WITHDRAWAL PERIODS

Withdrawal periods: Zero days

6. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 24 hours.

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd

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 SUBSTANCES

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

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

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

PARTICULARS TO APPEAR ON THE 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 substance:
Escherichia coli, recombinant Shiga toxin 2e: ≥ 3.2 x 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 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.

Overdose:

Following the administration of a double dose of vaccine no adverse reactions other than those described in section 6 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[1] Hyperthermia[2]
Uncommon (1 to 10 animals / 1,000 animals treated):	Behavioural disorders[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 at:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

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 (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 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

Vm 15052/5006

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. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder:

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

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

17. Other information

POM-V

Approved 20 November 2025

Gavin Hall