

# Biosuis Entero, Emulsion for injection

Authorised

- Porcine rotavirus A, strain OSU 6, Inactivated
- Escherichia coli, serotype O149:K88 (fimbrial adhesin F4ac), Inactivated
- Escherichia coli, serotype O101:K99 (fimbrial adhesins F5 and F41), Inactivated
- Escherichia coli, serotype K85:987P (fimbrial adhesin F6), Inactivated
- Clostridium perfringens, type C, beta toxoid

## Product identification

**Medicine name:**

Biosuis Entero, Emulsion for injection

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**Active substance:**

Porcine rotavirus A, strain OSU 6, Inactivated

Escherichia coli, serotype O149:K88 (fimbrial adhesin F4ac), Inactivated

Escherichia coli, serotype O101:K99 (fimbrial adhesins F5 and F41), Inactivated

Escherichia coli, serotype K85:987P (fimbrial adhesin F6), Inactivated

Clostridium perfringens, type C, beta toxoid

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**Target species:**

Pig

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**Route of administration:**

Intramuscular use

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## Product details

### **Active substance and strength:**

Porcine rotavirus A, strain OSU 6, Inactivated

1.00 relative potency / 1.00 Dose

Escherichia coli, serotype O149:K88 (fimbrial adhesin F4ac), Inactivated

1.00 relative potency / 1.00 Dose

Escherichia coli, serotype O101:K99 (fimbrial adhesins F5 and F41), Inactivated

1.00 relative potency / 1.00 Dose

Escherichia coli, serotype K85:987P (fimbrial adhesin F6), Inactivated

1.00 relative potency / 1.00 Dose

Clostridium perfringens, type C, beta toxoid

1.00 relative potency / 1.00 Dose

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### **Pharmaceutical form:**

Emulsion for injection

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### **Withdrawal period by route of administration:**

#### **Intramuscular use:**

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#### **Pig**

- Meat and offal. 0 day

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### **Anatomical therapeutic chemical veterinary (ATCvet) codes:**

QI09AL09

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### **Legal status of supply:**

Veterinary medicinal product subject to veterinary prescription

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### **Authorisation status:**

Valid

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### **Authorised in:**

Spain

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**Package description:**

Glass Vial 1 x 10.0 millilitre(s)

Glass Vial 1 x 50.0 millilitre(s)

Glass Vial 1 x 100.0 millilitre(s)

Plastic (HDPE) Vial 1 x 50.0 millilitre(s)

Plastic (HDPE) Vial 1 x 100.0 millilitre(s)

Plastic (HDPE) Vial 1 x 250.0 millilitre(s)

Glass Vial 10 x 10.0 millilitre(s)

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## Additional information

**Entitlement type:**

Marketing Authorisation

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**Legal basis of product authorisation:**

Full application (Article 12(3) of Directive No 2001/82/EC)

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**Marketing authorisation holder:**

Bioveta a.s.

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**Marketing authorisation date:**

24/04/2024

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**Manufacturing sites for batch release:**

Bioveta a.s.

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**Responsible authority:**

Spanish Agency Of Medicines And Medical Devices

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**Authorisation number:**

4310 ESP

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**Date of authorisation status change:**

25/04/2024

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**Reference member state:**

Czechia

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**Procedure number:**

**Concerned member states:**

Austria Belgium Bulgaria Denmark Estonia Finland France Germany  
Hungary Ireland Italy Latvia Lithuania Netherlands Norway Poland Portugal  
Romania Slovakia Spain Sweden United Kingdom (Northern Ireland)

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To consult adverse reactions on veterinary medicinal products please go to  
[www.adrreports.eu/vet](http://www.adrreports.eu/vet)

## Documents

### Summary of Product Characteristics

This document does not exist in this language (English). You can find it in another language below.

### Labelling

This document does not exist in this language (English). You can find it in another language below.

### Package Leaflet

This document does not exist in this language (English). You can find it in another language below.

Combined File of all Documents