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

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

Target species:
Pig

Route of administration:

Intramuscular use

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

Pharmaceutical form:
Emulsion for injection

Withdrawal period by route of administration:
Intramuscular use:

- **Pig**
  - Meat and offal. 0 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QI09AL09

Legal status of supply:
Veterinary medicinal product subject to veterinary prescription

Authorisation status:
Valid

Authorised in:
Germany

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)

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Full application (Article 12(3) of Directive No 2001/82/EC)

Marketing authorisation holder:
Bioveta a.s.

Marketing authorisation date:
23/04/2024

Manufacturing sites for batch release:
Bioveta a.s.

Responsible authority:
Paul-Ehrlich-Institut

Authorisation number:
PEI.V.12174.01.1

Date of authorisation status change:
23/04/2024

Reference member state:
Czechia

Procedure number:

CZ/V/0184/001

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)

To consult adverse reactions on veterinary medicinal products please go to www.adrreports.eu/vet

Documents

Combined File of all Documents

English (PDF)
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