SUIGEN ROTA COLI, EMULSION FOR INJECTION FOR PIGS

Authorised

- Escherichia coli, serotype K85:987P (fimbrial adhesin F6), Inactivated
- Escherichia coli, serotype O101:K99 (fimbrial adhesins F5 and F41), Inactivated
- Escherichia coli, serotype O149:K88 (fimbrial adhesin F4ac), Inactivated
- Porcine rotavirus A, strain OSU 6, Inactivated
- Escherichia coli, serotype O101:K99 (fimbrial adhesin F5), Inactivated
- Escherichia coli, serotype O147:K88 (fimbrial adhesin F4ab), Inactivated

Product identification

Medicine name:
SUIGEN ROTA COLI, EMULSION FOR INJECTION FOR PIGS

Active substance:
Escherichia coli, serotype K85:987P (fimbrial adhesin F6), Inactivated
Escherichia coli, serotype O101:K99 (fimbrial adhesins F5 and F41), Inactivated
Escherichia coli, serotype O149:K88 (fimbrial adhesin F4ac), Inactivated
Porcine rotavirus A, strain OSU 6, Inactivated
Escherichia coli, serotype O101:K99 (fimbrial adhesin F5), Inactivated
Escherichia coli, serotype O147:K88 (fimbrial adhesin F4ab), Inactivated

Target species:
Pig (for reproduction)

Route of administration:
Intramuscular use

Product details

Active substance and strength:
Escherichia coli, serotype K85:987P (fimbrial adhesin F6), Inactivated
1.00 relative potency / 2.00 millilitre(s)

Escherichia coli, serotype O101:K99 (fimbrial adhesins F5 and F41), Inactivated
1.00 relative potency / 2.00 millilitre(s)

Escherichia coli, serotype O149:K88 (fimbrial adhesin F4ac), Inactivated
1.00 relative potency / 2.00 millilitre(s)

Porcine rotavirus A, strain OSU 6, Inactivated
1.00 relative potency / 2.00 millilitre(s)

Escherichia coli, serotype O101:K99 (fimbrial adhesin F5), Inactivated
1.00 relative potency / 2.00 millilitre(s)

Escherichia coli, serotype O147:K88 (fimbrial adhesin F4ab), Inactivated
1.00 relative potency / 2.00 millilitre(s)

Pharmaceutical form:
Emulsion for injection

Withdrawal period by route of administration:
Intramuscular use:

- **Pig (for reproduction)**
  - All relevant tissues. 0 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QI09AL02

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:
Valid

Authorised in:
Germany

Available in:
Germany

Package description:
Cardboard box 1 × 10 ml (1 x 5 doses) in 10 ml glass vial hydrolytic class I
Cardboard box 1 × 50 ml (1 x 25 doses) in 50 ml glass vial hydrolytic class II
Cardboard box 1 × 50 ml (1 x 25 doses) in 60 ml HDPE plastic vial
Cardboard box 1 × 100 ml (1 x 50 doses) in 100 ml glass vial hydrolytic class II
Cardboard box 1 × 100 ml (1 x 50 doses) in 120 ml HDPE plastic vial
Cardboard box 1 × 250 ml (1 x 125 doses) in 250 ml HDPE plastic bottle
Plastic box 10 × 10 ml (10 x 5 doses) in 10 ml glass vial hydrolytic class I

Additional information

Entitlement type:
Marketing Authorisation

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

Marketing authorisation holder:
Virbac

Marketing authorisation date:
20/06/2022

Manufacturing sites for batch release:
Bioveta a.s.

Responsible authority:
Paul-Ehrlich-Institut

Authorisation number:
PEI.V.12117.01.1

Date of authorisation status change:
20/06/2022

Reference member state:
France

Procedure number:
FR/V/0446/001

Concerned member states:
Germany

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

Documents

Package Leaflet

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

Summary of Product Characteristics

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

Combined File of all Documents

eu-puar-frv0446001-mr-rpe703-en.pdf

7005808-paren-20220601.pdf