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Bovilis Rotavec Corona Emulsion for Injection for Cattle

Authorised

- Escherichia coli, serotype O101:K99 (fimbrial adhesins F5 and F41), strain CN7985, Inactivated
- Bovine rotavirus A, type G6P5, strain UK-Compton, Inactivated
- Bovine coronavirus, strain Mebus, Inactivated

Product identification

Medicine name:
Bovilis Rotavec Corona Emulsion for Injection for Cattle

Active substance:
Escherichia coli, serotype O101:K99 (fimbrial adhesins F5 and F41), strain CN7985, Inactivated

Bovine rotavirus A, type G6P5, strain UK-Compton, Inactivated

Bovine coronavirus, strain Mebus, Inactivated

Target species:
Cattle

Route of administration:
Intramuscular use
Subcutaneous use

Product details

Active substance and strength:

Escherichia coli, serotype O101:K99 (fimbrial adhesins F5 and F41), strain CN7985, Inactivated

560.00 enzyme-linked immunosorbent assay unit / 2.00 millilitre(s)

Bovine rotavirus A, type G6P5, strain UK-Compton, Inactivated

874.00 enzyme-linked immunosorbent assay unit / 2.00 millilitre(s)

Bovine coronavirus, strain Mebus, Inactivated

340.00 enzyme-linked immunosorbent assay unit / 2.00 millilitre(s)

Pharmaceutical form:

Emulsion for injection

Withdrawal period by route of administration:

Intramuscular use:

- **Cattle**
  - Meat and offal. 0 day
  - Milk. 0 day

Subcutaneous use:

- **Cattle**
  - Meat and offal. 0 day
  - Milk. 0 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QI02AL01

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

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Authorisation status:

Valid

Authorised in:
Norway

Available in:
Norway

Package description:
(ID7) 100 millilitre(s): Box with 1 Vial (polyethylene terephthalate) with 100 millilitre(s), closed with Cap`` (aluminium) and Stopfen (butyl rubber)
(ID6) 40 millilitre(s): Box with 1 Vial (polyethylene terephthalate) with 40 millilitre(s), closed with Stopfen (butyl rubber) and Cap`` (aluminium)
(ID5) 10 millilitre(s): Box with 1 Vial (polyethylene terephthalate) with 10 millilitre(s), closed with Stopfen (butyl rubber) and Cap`` (aluminium)
(ID1) 20 millilitre(s): Box with 10 Vial (Glass type I) each with 2 millilitre(s), closed with Stopfen (Halobutyl Rubber) and Cap`` (aluminium)
(ID2) 10 millilitre(s): Box with 1 Vial (Glass type I) with 10 millilitre(s), closed with Stopfen (Halobutyl Rubber) and Cap`` (aluminium)
(ID4) 100 millilitre(s): Box with 1 Vial (Glass type I) with 100 millilitre(s), closed with Stopfen (Halobutyl Rubber) and Cap`` (aluminium)
(ID3) 40 millilitre(s): Box with 1 Vial (Glass type I) with 40 millilitre(s), closed with Stopfen (Halobutyl Rubber) and Cap`` (aluminium)

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Immunological veterinary medicinal product application (Article 13d of Directive No 2001/82/EC)

Marketing authorisation holder:
Intervet International B.V.

Marketing authorisation date:
17/07/2020

Manufacturing sites for batch release:

Intervet International B.V.

Responsible authority:
Norwegian Medical Products Agency

Authorisation number:
20-13257

Date of authorisation status change:
17/07/2020

Reference member state:
Germany

Procedure number:
DE/V/0276/001

Concerned member states:
Austria Belgium Bulgaria Cyprus Czechia Denmark Estonia Finland France Greece Hungary Ireland Italy Latvia Lithuania Luxembourg Malta Netherlands Norway Poland Portugal Romania Slovakia Slovenia Spain Sweden United Kingdom (Northern Ireland)

To consult adverse reactions on veterinary medicinal products please go to 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.

Combined File of all Documents