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

# Product identification

#### **Medicine name:**

Bovilis Rotavec Corona Emulsion for Injection for Cattle

Bovilis Rotavec Corona Emulsie voor injectie

Bovilis Rotavec Corona Emulsion injectable

Bovilis Rotavec Corona Emulsion zur Injektion

#### **Active substance:**

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

Bovine coronavirus, strain Mebus, Inactivated

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

#### **Target species:**

Cattle

#### Route of administration:

Intramuscular 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 coronavirus, strain Mebus, Inactivated

340.00 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)

#### **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

#### **Authorisation status:**

Valid

#### **Authorised in:**

Belgium

#### Package description:

(ID3) 40 millilitre(s): Box (Cardboard) with 1 Vial (Glass) with 40 millilitre(s)

(ID4) 100 millilitre(s): Box (Cardboard) with 1 Vial (Glass) with 100 millilitre(s)

(ID2) 10 millilitre(s): Box (Cardboard) with 1 Vial (Glass) with 10 millilitre(s)

(ID1) 20 millilitre(s): Box (Cardboard) with 10 Vial (Glass) each with 2 millilitre(s)

(ID5) 10 millilitre(s): Box (Cardboard) with 1 Vial (PolyEthylene TerePhthalate) with 10 millilitre(s)

(ID6) 40 millilitre(s): Box (Cardboard) with 1 Vial (PolyEthylene TerePhthalate) with 40 millilitre(s)

(ID7) 100 millilitre(s): Box (Cardboard) with 1 Vial (PolyEthylene TerePhthalate) with 100 millilitre(s)

# 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:

11/01/2021

# Manufacturing sites for batch release:

Burgwedel Biotech GmbH

Intervet International B.V.

# Responsible authority:

#### Federal Agency For Medicines And Health Products

#### **Authorisation number:**

This information is not available for this product.

#### Date of authorisation status change:

11/01/2021

#### **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

English (PDF)

Published on: 28/01/2022

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Package Leaflet
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Labelling
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Combined File of all Documents