

BioBos RCC, Suspension for injection

Authorised

- Bovine coronavirus, strain C-197, Inactivated
- Bovine rotavirus A, type G6P1, strain TM-91, Inactivated
- Escherichia coli, serotype O8:K35 (fimbrial adhesin F5), Inactivated

Product identification

Medicine name:

BioBos RCC, Suspension for injection

Active substance:

Bovine coronavirus, strain C-197, Inactivated

Bovine rotavirus A, type G6P1, strain TM-91, Inactivated

Escherichia coli, serotype O8:K35 (fimbrial adhesin F5), Inactivated

Target species:

Cattle

Route of administration:

Intramuscular use

Product details

Active substance and strength:

Bovine coronavirus, strain C-197, Inactivated

1.00 relative potency / 1.00 Dose

Bovine rotavirus A, type G6P1, strain TM-91, Inactivated

1.00 relative potency / 1.00 Dose

Escherichia coli, serotype O8:K35 (fimbrial adhesin F5), Inactivated

1.00 relative potency / 1.00 Dose

Pharmaceutical form:

Suspension for injection

Withdrawal period by route of administration:

Intramuscular use:

-

Cattle

- Meat and offal. 0 day

- Milk. 0 hour

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QI02AL01

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Estonia

Package description:

Glass Vial 2 x 1.0 Dose

Glass Vial 10 x 1.0 Dose

Glass Vial 20 x 1.0 Dose

Glass Vial 1 x 5.0 Dose

Plastic Vial 1 x 5.0 Dose

Glass Vial 5 x 5.0 Dose

Plastic Vial 5 x 5.0 Dose

Glass Vial 10 x 5.0 Dose
Plastic Vial 10 x 5.0 Dose
Glass Vial 1 x 25.0 Dose
Plastic Vial 1 x 25.0 Dose
Glass Vial 12 x 25.0 Dose
Plastic Vial 12 x 25.0 Dose
Glass Vial 24 x 25.0 Dose
Plastic Vial 24 x 25.0 Dose
Glass Vial 1 x 50.0 Dose
Plastic Vial 1 x 50.0 Dose

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:

29/06/2022

Manufacturing sites for batch release:

Bioveta a.s.

Responsible authority:

State Agency Of Medicines

Authorisation number:

2366

Date of authorisation status change:

29/06/2022

Reference member state:

Czechia

Procedure number:

CZ/V/0176/001

Concerned member states:

Bulgaria Croatia Cyprus Estonia Hungary Latvia Lithuania Malta Poland
Romania Slovakia

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

eu-puar-czv0176001-mr-biobos_rcc-en.pdf

PuAR Biobos RCC.pdf