ROTAGAL emulsion for injection

Authorised

- Escherichia coli, fimbrial adhesin F5
- Bovine coronavirus, strain C-197, Inactivated
- Bovine rotavirus A, type G6P1, strain TM-91, Inactivated

Product identification

Medicine name:
ROTAGAL emulsion for injection
ROTAGAL, Injekční emulze

Active substance:
Escherichia coli, fimbrial adhesin F5

Bovine coronavirus, strain C-197, Inactivated

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

Target species:
Cattle (pregnant cow)

Route of administration:
Intramuscular use

Product details

Active substance and strength:
Escherichia coli, fimbrial adhesin F5
39.70 enzyme-linked immunosorbent assay unit / 3.00 millilitre(s)

Bovine coronavirus, strain C-197, Inactivated
44.80 enzyme-linked immunosorbent assay unit / 3.00 millilitre(s)

Bovine rotavirus A, type G6P1, strain TM-91, Inactivated
32.10 enzyme-linked immunosorbent assay unit / 3.00 millilitre(s)

Pharmaceutical form:
Emulsion for injection

Withdrawal period by route of administration:
Intramuscular use:

- **Cattle (pregnant cow)**
  - All relevant tissues. 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:
Czechia

Package description:
Available only in Slovak
Available only in Slovak
Available only in Slovak
Available only in Slovak
Available only in Slovak

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:
Pharmagal Bio spol. s r.o.

Marketing authorisation date:
11/07/2008

Manufacturing sites for batch release:
Pharmagal Bio spol. s r.o.

Responsible authority:
Institute For State Control Of Veterinary Biologicals And Medicaments

Authorisation number:
97/041/08/C

Date of authorisation status change:
11/07/2008

Reference member state:
Slovakia

Procedure number:
SK/V/0105/001

Concerned member states:
Czechia

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

Documents

Combined File of all Documents

Summary of Product Characteristics

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

Package Leaflet

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

Labelling

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