

BOVIGEN SCOUR Emulsion for injection for cattle

Authorised

- Bovine coronavirus, strain C-197, Inactivated
- Bovine rotavirus A, type G6P1, strain TM-91, Inactivated
- Escherichia coli, serotype O9:K35 (fimbrial adhesin F5 and F41), strain EC/17, Inactivated

Product identification

Medicine name:

BOVIGEN SCOUR Emulsion for injection for cattle

Active substance:

Bovine coronavirus, strain C-197, Inactivated

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

Escherichia coli, serotype O9:K35 (fimbrial adhesin F5 and F41), strain EC/17, Inactivated

Target species:

Cattle

Route of administration:

Intramuscular use

Product details

Active substance and strength:

Bovine coronavirus, strain C-197, Inactivated

5.00 log₂ haemagglutination inhibiting unit(s) / 1.00 Dose

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

6.00 log₂ virus neutralising unit(s) / 1.00 Dose

Escherichia coli, serotype O9:K35 (fimbrial adhesin F5 and F41), strain EC/17, Inactivated

44.80 enzyme-linked immunosorbent assay unit / 1.00 Dose

Pharmaceutical form:

Emulsion for injection

Withdrawal period by route of administration:

Intramuscular use:

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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:

Germany

Available in:

Germany

Package description:

Glass bottle, type I (450 ml) closed with bromobutyl rubber stoppers sealed with aluminium caps. Package size: Cardboard box with 1 glass bottle of 450 ml (150 doses), type I (450 ml) closed with bromobutyl rubber stoppers sealed with aluminium caps.

Glass vials, type I (90 ml) closed with chlorobutyl rubber stoppers. Package size: Cardboard box with 1 vial of 90 ml (30 doses), type I (90 ml) closed with chlorobutyl rubber stoppers

Glass vials, type I (15 ml) closed with chlorobutyl rubber stoppers. Package size: Cardboard box with 1 vial of 15 ml (5 doses), type I (15 ml) closed with chlorobutyl rubber stoppers

Glass bottle, type I (450 ml) closed with bromobutyl rubber stoppers sealed with aluminium caps. Package size: Plastic bottle with 450 ml (150 doses) closed with chlorobutyl rubber stoppers and sealed with aluminium caps without outer package

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:

Forte Healthcare Limited

Marketing authorisation date:

24/02/2015

Manufacturing sites for batch release:

Pharmagal Bio spol. s r.o.

Responsible authority:

Paul-Ehrlich-Institut

Authorisation number:

PEI.V.11715.01.1

Date of authorisation status change:

12/08/2020

Reference member state:

Ireland

Procedure number:

IE/V/0341/001

Concerned member states:

Austria Belgium Croatia Cyprus Denmark Estonia Finland France Germany
Greece Italy Latvia Lithuania Luxembourg Malta Netherlands Norway
Portugal Romania Slovenia Spain Sweden United Kingdom (Northern Ireland)

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

Documents

Combined File of all Documents

English (PDF)

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Summary of Product Characteristics