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Rovac -rotavirus bydlęcy, szczep TM-91, serotyp G6P1 (inaktywowany): 2/3 dawki szczepionki indukuje ≥ 6,0 log2 (VNT)*;-koronawirus bydlęcy, szczep C-197 (inaktywowany): 2/3 dawki szczepionki indukuje ≥ 5,0 log2 (HIT)**;-adhezyna E.coli F5 (K99): 2/3 dawki indukuje ≥ 40% hamowania (ELISA)***;* VNT-Test neutralizacji wirusa,**HIT- Test hamowania hemaglutynacji,***ELISA- enzymatyczny test immunosorpcyjny. Emulsja do wstrzykiwań

Authorised

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

Product identification

Medicine name:
Rovac -rotavirus bydlęcy, szczep TM-91, serotyp G6P1 (inaktywowany): 2/3 dawki szczepionki indukuje ≥ 6,0 log2 (VNT)*;-koronawirus bydlęcy, szczep C-197 (inaktywowany): 2/3 dawki szczepionki indukuje ≥ 5,0 log2 (HIT)**;-adhezyna E.coli F5 (K99): 2/3 dawki indukuje ≥ 40% hamowania (ELISA)***;* VNT-Test neutralizacji wirusa,**HIT- Test hamowania hemaglutynacji,***ELISA- enzymatyczny test immunosorpcyjny. Emulsja do wstrzykiwań

Active substance:
Bovine rotavirus A, type G6P1, strain TM-91, Inactivated

Bovine coronavirus, strain C-197, Inactivated

Escherichia coli, fimbrial adhesin F5

Target species:
Cattle

Route of administration:
Intramuscular use

Product details

Active substance and strength:
Bovine rotavirus A, type G6P1, strain TM-91, Inactivated
2.58 unknown / 2.00 millilitre(s)

Bovine coronavirus, strain C-197, Inactivated

Escherichia coli, fimbrial adhesin F5
40.00 enzyme-linked immunosorbent assay unit / 2.00 millilitre(s)

Pharmaceutical form:
Emulsion for injection/infusion

Withdrawal period by route of administration:
Intramuscular use:

- **Cattle**
  - Meat and offal. 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:
Poland

Package description:
Available only in Polish
Available only in Polish
Available only in Polish
Available only in Polish
Available only in Polish

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 spol. s r.o.

Marketing authorisation date:
5/12/2016

Manufacturing sites for batch release:

Pharmagal Bio spol. s r.o.

Responsible authority:
Office For Registration Of Medicinal Products Medical Devices And Biocidal Products

Authorisation number:
2607

Date of authorisation status change:
5/12/2016

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

Documents

Labelling

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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.

Package Leaflet and Labelling

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