FOR VETERINARY USE ONLY

ROCODOLL

INACTIVATED VACCINE AGAINST ROTA, CORONA AND E.COLI INFECTIONS IN CATTLE

Dollvet

SUSPENSION FOR INJECTION

COMPOSITION:

Active Substances

For each dose of vaccine:

Inactive Bovine rotavirus (BRV) strain G6 P(1)	ELISA ≥2.1 log_{10}*
Inactive Bovine rotavirus (BRV) strain G10 P(11)	ELISA ≥2.1 log_{10}*
Inactive Bovine rotavirus (BRV) strain G8 P(5)	ELISA ≥2.1 log_{10}*
Inactive Bovine coronavirus (BCoV) strain	ELISA ≥2.1 log_{10}*
Inactive E.coli EC (O101: H-K99+F41+) strain	SAT≥ 2.2 log_{10}** (for K99 antigen)
Inactive E.coli 11A (O?:H-K99+:F(Y)+) strain	SAT≥ 2.2 log_{10}** (for K99 antigen)

* ELISA: ELISA titer in guinea pigs vaccinated with ½ cattle dose

**SAT: Serum agglutination titer in guinea pigs vaccinated with ½ cattle dose

EXCIPIENTS:

Aluminum hydroxide (Al^{+3})	1.5 mg/ml
Saponin	0.3 mg/ml

INDICATIONS:

It is an inactivated vaccine administered to pregnant cows and heifers for passive immunization in calves against neonatal diarrhea, caused by *Escherichia coli*, rotavirus and coronavirus.

ADMINISTRATION METHOD AND DOSAGE:

The vaccine is administered to pregnant cows twice: the first in the 7th-8th month of pregnancy, the latter 3 weeks after the first one, both by subcutaneous injection of 5 ml. In subsequent pregnancies, it is recommended to administer one dose 3-6 weeks prior to delivery.

SPECIFIC CLINICAL INFORMATION AND WARNINGS FOR TARGET SPECIES:

Animals to be vaccinated must be in good health.
The vial should be well shaken before use.
The vaccine should be brought to room temperature before administration.
Aseptic needles and syringes should be used in every application.

Use in Pregnancy and Lactation:

It is safe to be administered in the last trimester of pregnancy. Its use in lactation does not fall within the indications of the product.

ADVERSE REACTIONS:

In some animals, a temporary nodule may form at the vaccine administration site. In rare cases of anaphylactic reaction in susceptible animals, symptomatic treatment (antihistaminic/ antiallergic drugs) should be applied.

INTERACTION WITH OTHER MEDICINAL PRODUCTS:

No information is available on the compatibility of this product when used with other vaccines. Its use on the same day or at different times with other products has not been proven to be effective or safe.

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OVERDOSE SYMPTOMS, EMERGENCY PROCEDURES AND ANTIDOTES:
No overdose studies have been conducted, as it is an inactivated vaccine.

WITHDRAWAL PERIODS:
Zero (0) days.

CONTRAINDICATIONS:
The vaccine has no known contraindications.

GENERAL WARNINGS:
Keep out of reach of children.
Consult a veterinarian before use and upon an unexpected effect.

PRECAUTIONS TO BE TAKEN BY THE PERSON ADMINISTERING THE VACCINE AND RECOMMENDATIONS FOR VETERINARIANS:
It has no known negative effects on human health. However, in case of an accidental injury during administration, the site should be cleaned and disinfected.
The vaccine should only be administered by a veterinarian or a veterinary technician under the supervision of a veterinarian.

STORAGE CONDITIONS AND SHELF LIFE:
Stored at + 2/8°C, and in the dark. Do not freeze.
Shelf life is 24 months. Opened vials should be used within 6-8 hours.

WARNINGS FOR DISPOSAL AND NON-TARGET SPECIES:
After the use of products, residual materials should be disposed of by boiling, incineration or dipping in an appropriate disinfectant.

PRESENTATION:
The vaccine is packaged in 5, 25, 50 and 100 ml type II glass bottles and 50 and 100 ml polypropylene plastic bottles, as 1 dose, 5 doses, 10 doses and 20 doses. Vaccine bottles are available on the market as 5 ml / 1 dose in single-pack cardboard boxes, 10-pack cardboard boxes or plastic vials: 25 ml / 5 doses, 50 ml / 10 doses and 100 ml / 20 doses of glass and plastic packs in single-unit cardboard boxes or as packaged in styrofoam without boxes. Not all forms of packaging may be placed on the market.

LEAFLET APPROVAL DATE: 05.07.2021

DATE OF MARKETING AUTHORIZATION ISSUED BY MINISTRY OF AGRICULTURE AND FORESTRY: 05.07.2021

NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER:
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