United Kingdom
Veterinary Medicines Directorate
Woodham Lane
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Surrey KT15 3LS

NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

DiarrVac RCE Emulsion for Injection for Cattle

Date Created:
May 2022

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	DiarrVac RCE Emulsion for Injection for Cattle
Applicant	Forte Healthcare Ltd Cougar Lane Naul Co. Dublin Ireland
Active substance(s)	Bovine rotavirus strain TM-91, serotype G6P1 (inactivated) Bovine coronavirus strain C-197 (inactivated) *Escherichia coli* strain EC/17 (inactivated)
ATC Vetcode	QI02AL01
Target species	Cattle (pregnant cows and heifers)
Indication for use	For the active immunisation of pregnant cows and heifers to raise antibodies against E. coli adhesion F5 (K 99) antigen, rotavirus and coronavirus. When calves are fed colostrum from vaccinated cows during the first week of life, these antibodies have been demonstrated to reduce the severity of diarrhoea caused by bovine rotavirus, bovine coronavirus and enteropathogenic E. coli F5 (K99) and to reduce the shedding of virus by calves infected with bovine rotavirus or bovine coronavirus. Onset of immunity: Passive immunity commences with colostrum feeding and is dependent on calves receiving sufficient colostrum after birth.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Product Information Database of the Veterinary Medicines Directorate.

(www.gov.uk/check-animal-medicine-licensed)

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Informed Consent application in accordance with Article 13c of Directive 2001/82/EC as amended
Date of conclusion of the procedure	11/03/2022

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of this product is / are identical to Bovigen Scour Emulsion for Injection for Cattle.

II. OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics, the benefit/risk profile of the product is favourable.

MODULE 4

POST- AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the Product Information Database of the Veterinary Medicines Directorate website.

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The post-authorisation assessment (PAA) contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

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