IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

DiarrVac RCE Emulsion for injection for cattle.

PRODUCT SUMMARY

EU Procedure number	IE/V/0777/001/DC
Name, strength and pharmaceutical form	DiarrVac RCE Emulsion for injection for cattle.
Active substances(s)	Bovine rotavirus, Inactivated,Bovine coronavirus, Inactivated,Escherichia Coli (Inactivated)
Applicant	FORTE Healthcare Ltd Cougar Lane Naul Co. Dublin Ireland
Legal basis of application	Informed consent application in accordance with Article 13 (c) of Directive No 2001/83/EC as amended.
Date of Authorisation	11/02/2022
Target species	Cattle
Indication for use	For the active immunisation of pregnant cows and heifers to provide passive immunity to calves via colostrum/milk 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.
ATCvet code	QI02AL01
Concerned Member States	UK(NI)

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the HPRA at the end of the evaluation process and provides a summary of the grounds for approval of the marketing authorisation for the specific veterinary medicinal product. It is made available by the HPRA for information to the public, after the deletion of commercially confidential information. The legal basis for its creation and availability is contained in Article 25.4 of EC Directive 2001/82/EC as amended by Directive 2004/28/EC for veterinary medicinal products. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the product for marketing in Ireland.

The Summary of Product Characteristics (SPC) for this product is available on the HPRA's website.

I. SCIENTIFIC OVERVIEW

The quality, safety and efficacy aspects of this product are identical to Bovigen Scour Emulsion for injection for cattle.

The product is produced and controlled using validated methods and tests, which ensure the consistency of the product released on the market.

It has been shown that the product can be safely used in the target species.

The product is safe for the user, the consumer of foodstuffs from treated animals and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.

The efficacy of the product was demonstrated according to the claims made in the SPC.
The overall benefit/risk analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

See section 1.

III. SAFETY ASSESSMENT

See section I.

IV. CLINICAL ASSESSMENT

See section I.

V. OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

On the basis of the original data submitted, the HPRA considered that the product demonstrated adequate evidence of efficacy for the approved indications as well as a satisfactory benefit/risk profile and therefore granted a marketing authorisation.

VI. 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 HPRA website.