Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
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MUTUAL RECOGNITION PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Rotavec Corona Emulsion for Injection for Cattle

PuAR correct as of 14/12/2017 when RMS was transferred to DE. Please contact the RMS for future updates

MODULE 1

PRODUCT SUMMARY

EU Procedure number	UK/V/0138/001/E001
Name, strength and pharmaceutical form	Rotavec Corona Emulsion for Injection for Cattle
Applicant	Intervet UK Ltd Walton Manor Walton Milton Keynes Buckinghamshire MK7 7AJ
Active substance(s)	Per 2 ml dose: **Active Substances** Bovine rotavirus, strain UK-Compton, serotype G6 P5 (inactivated) — ¼ dose of vaccine stimulates a virus neutralising antibody titre: ≥ 7.7 $\log_2$/ml (guinea pigs). Bovine coronavirus, strain Mebus (inactivated) — 1/20 dose of vaccine stimulates an ELISA antibody titre: ≥ 3.41 $\log_{10}$/ml (guinea pigs). *E. coli* F5 (K99) adhesin — 1/20 dose of vaccine stimulates an ELISA antibody (OD492): > 0.64 (guinea pigs).
ATC Vetcode	Q102AL01
Target species	Cattle
Indication for use	For the active immunisation of pregnant cows and heifers to raise antibodies against *E. coli* adhesin F5 (K99) antigen, rotavirus and coronavirus. While calves are fed colostrum from vaccinated cows during the first two to four weeks of life, these antibodies have been demonstrated to: - reduce the severity of diarrhoea caused by *E. coli* F5 (K99) - reduce the incidence of scours caused by rotavirus - reduce the shedding of virus by calves

	infected with rotavirus or coronavirus. Onset of Immunity : Passive protection against all active substances will commence from the start of colostrum feeding Duration of Immunity : In calves artificially fed with pooled colostrum, protection will continue until colostrum feeding ceases. In naturally suckled calves, protection against rotavirus will persist for at least 7 days and against coronavirus for at least 14 days.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Medicines Agencies (veterinary) (HMA(v)) website (www.hma.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Mutual recognition application in accordance with Article 13 (3) of Directive 2001/82/EC as amended.
Date of completion of the original mutual recognition procedure	16th March 2000
Date product first authorised in the Reference Member State (MRP only)	12 April 1999.
Concerned Member States for original procedure	Austria, Belgium, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain
Date of completion of the repeat-use mutual recognition procedure	3 April 2008
Concerned Member States for repeat use procedure	Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Romania, Slovakia, Slovenia, Sweden

I. SCIENTIFIC OVERVIEW

The product is an inactivated adjuvanted vaccine emulsion for injection, for intramuscular administration to pregnant cows and heifers, in order to raise antibodies against the *Escherichia coli* adhesion F5 (K99) antigen, and specific coronavirus and rotavirus strains. Calves fed colostrum from vaccinated animals show a reduced incidence of scour caused by rotavirus, reduced viral shedding of coronavirus or rotavirus, and reduction of the severity of diarrhoea caused by *E. coli* F5 (K99). In naturally suckled calves, rotaviral protection persists for at least 7 days, and persists against coronavirus for at least 14 days.

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 slight reactions observed are indicated in the SPC[1]. 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

[1] SPC – Summary of Product Characteristics.

made in the SPC.

The overall benefit/risk analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Composition

The product contains:-

Bovine rotavirus, strain UK-Compton, serotype G6 P5 (inactivated)	¼ dose of vaccine stimulates a virus neutralising antibody titre: ≥ 7.7 $\log_2$/ml (guinea pigs).
Bovine coronavirus, strain Mebus (inactivated)	1/20 dose of vaccine stimulates an ELISA antibody titre: ≥ 3.41 $\log_{10}$/ml (guinea pigs).
E. coli F5 (K99) adhesin	1/20 dose of vaccine stimulates an ELISA antibody (OD492): > 0.64 (guinea pigs).

The adjuvants are light mineral oil and aluminium hydroxide, and the excipients are thiomersal, formaldehyde, sodium thiosulphate and sodium chloride.

The particulars of the containers and controls performed are provided and conform to the regulation. The choice of the adjuvants, vaccine strains, inactivating agent and the presence of preservative are justified. The inactivation process and the detection limit of the control of inactivation are correctly validated.

The product is of an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

B. Method of Preparation of the Product

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site. Process validation data on the product have been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials

The active substances are inactivated bovine rotavirus, bovine coronavirus and the *E.coli* F5 (K99) adhesion. The active substances are manufactured in accordance with the principles of good manufacturing practice. Starting materials of biological and/or non-biological origin used in production comply with appropriate control data.

The master and working seeds have been produced according to the Seed Lot System as described in the relevant guideline.

D. Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

Scientific data and/or certificates of suitability issued by the EDQM have been provided and compliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products has been satisfactorily demonstrated.

E. Control tests during production

The tests performed during production are described and the results of 3 consecutive runs, conforming to the specifications, are provided.

F. Control Tests on the Finished Product

The tests performed on the final product conform to the relevant requirements; any deviation from these requirements was justified.

G. Stability

Stability data on the active substances have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

Store and transport refrigerated (2° C – 8° C).
Protect from light.
Do not freeze.

III. SAFETY ASSESSMENT

Laboratory trials

The safety of the administration of one dose, an overdose and the repeated administration of one dose in the target animal was demonstrated. The investigation was performed according to the recommendations of Directive 2001/82/EC as amended and the relevant guidelines.

Effects on reproductive performance were examined. The product may be used during pregnancy. The vaccine is inactivated. An appropriate warning in the SPC is included barring the user from mixing the products with any other medicinal product.

Field studies

Appropriate field studies were conducted.

Ecotoxicity

The applicant provided an appropriate risk assessment in compliance with the relevant guideline.
Warnings and precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed.

IV CLINICAL ASSESSMENT (EFFICACY)

Clinical Studies

Laboratory Trials

The efficacy of the product has been demonstrated in laboratory studies in accordance with the relevant requirements.

Dose confirmation studies

Suitable studies were provided.

Field Trials

Suitable studies were provided.

V 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 for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

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.

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

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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