Veterinary Medicines Directorate

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Post Authorisation Assessments

Bovilis Rotavec Corona Emulsion for Injection for Cattle

Vm 01708/3043

•	05 December 2023	To add Intervet International B.V. (Boxmeer, the Netherlands) as alternative secondary packaging site.
•	05 December 2023	To increase the batch size from 90 - 1800 litres to 90 - 2250 litres. To include Intervet International BV, Boxmeer, Netherlands as an additional batch release site. To include MSD AH Danube Biotech GmbH, Krems, Austria as an additional site for QC testing on final product. To include MSD AH Danube Biotech GmbH, Krems, Austria as an additional site for Formulation and filling final product.
•	11 August 2023	To increase the batch size. To include Intervet International BV, Boxmeer, Netherlands as an additional batch release site. To include MSD AH Danube Biotech GmbH, Krems, Austria as an additional site for QC testing on final product. To include MSD AH Danube Biotech GmbH, Krems, Austria as an additional site for Formulation and filling final product.
•	24 November 2022	Replacement of current E. coli agglutination assays for identity and antigen content with an E. coli antigen content ELISA. Replacement of in vivo potency test for BCV with antigen specific in vitro potency ELISA. Replacement of in vivo potency test for E. coli with antigen specific in vitro potency ELISA. Addition of Intervet International B.V., Boxmeer (NL) for in-process quality control testing for the E. coli, BRV and BCV antigens. Changes in the E.coli and bovine coronavirus antigen contents to 340 and 560 U/dose respectively in SPC, labelling and package leaflet. Change in the information on the characterisation of the E. coli strain in the vaccine from E.coli F5 to E.coli strain CN7985.
•	21 October 2021	Deletion of a non-significant in-process test applied during the manufacture of the active substance. Deletion of a non-significant in-process test applied during the manufacture of the active substance. Changes to a test procedure for the active substance. Submission of a new Ph. Eur. TSE certificate of

		suitability (used in manufacturing process of active) from a new manufacturer. Qualitative composition changes to the immediate packaging of the active substance. Change in the manufacturer used in the manufacturing process of the active. Change in the manufacturing process of the active substance.
•	22 February 2021	Changes to the labelling and/or package leaflet.
•	26 November 2020	Change in the invented name of the veterinary medicinal product from Rotavec Corona Emulsion for Injection for Cattle to Bovilis Rotavec Corona Emulsion for Injection for Cattle. Increase in the shelf-life of the finished product after first opening, from 8 hours to 28 days. Changes in the qualitative and quantitative composition of the immediate packaging of the finished product. Change in the fill volume of the finished product. Replacement of a test procedure for the active substance. Replacement of a test procedure for the finished product.
•	14 August 2020	Change in the name of the marketing authorisation holder from Intervet UK Limited to MSD Animal Health UK Limited.
•	13 November 2018	Change in the safety database of an existing pharmacovigilance system as described in the DDPS
•	14 August 2018	Editorial changes to the registered dossier, detailing the manufacturing filtration step.
•	11 April 2018	Repeat Use to add 1 new CMS
•	14 December 2017	Change in RMS from UK to DE.
•	16 December 2016	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	22 May 2015	Variation to include an additional manufacturing site and editorial corrections in the description of the manufacturing process
•	22 May 2015	Change in the manufacturing process of the active substance.
•	04 December 2014	Update to the DDPS.
•	19 September 2014	Change in test procedure for the active substance.
•	09 January 2014	Variation to change the end of shelf life specification, and to make minor editorial changes.
•	12 August 2013	Deletion of the aluminium content during stability testing.
•	17 November 2011	Change in the immediate packaging of the finished product.
•	04 August 2011	Change of the name of the Marketing Authorisation Holder in Portugal only.
•	06 April 2011	Change in the name and/or address of the manufacturer of the finished product.
•	10 September 2010	Introduction of a new pharmacovigilance system.
•	25 August 2010	Renewal.

•	29 April 2010	Change of Marketing Authorisation Holder and distributor.
•	21 October 2009	Simple text changes to SPC and product literature.
•	14 August 2009	Change of Marketing Authorisation Holder name and address in France only.
•	03 April 2008	Repeat Use.
•	25 October 2006	Change in TSE risk documents.
•	03 August 2006	To change the pack size.
•	01 July 2005	Renewal.
•	04 November 2004	Increased shelf life of the finished product.
•	08 October 2003	Change of specification of the active component.
•	06 June 2003	Addition of three suppliers of a starting material.
•	06 June 2003	Addition of a supplier of a starting material.
•	07 February 2002	Change in the manufacturing process.