Veterinary Medicines Directorate

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Post Authorisation Assessments

Endospec SC 10% w/v Oral Suspension

Vm 50146/4025

•	03 March 2023	Approval of mock ups.
•	17 November 2022	Replacement of a quality testing site.
•	14 April 2022	Tightening of specification limits of the immediate packaging of the finished product.
•	26 January 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	17 September 2020	Changes to the labelling and/or package leaflet.
•	21 August 2020	Deletion of manufacturing site responsible for batch release.
•	23 January 2020	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product.
•	24 July 2019	Change in the name of a manufacturer used in the manufacture of the active substance. Change in the name and/or address of a manufacturer of the finished product, also responsible for batch release.
•	19 June 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	24 October 2018	Change of MAH, from Cross Vetpharm Group Ltd., Broomhill Road, Tallaght, Dublin 24, Ireland to Bimeda Animal Health Limited, 2 / 3 / 4 Airton Close, Tallaght, Dublin 24, Ireland. Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	10 July 2018	Change in specifications from a national pharmacopoeia of a Member State to the Ph. Eur.
•	19 May 2017	Change in the number of units in a pack within the range of the currently approved pack sizes of the finished product Deletion of a pack sizes of the finished product. Changes in the qualitative and quantitative composition of the immediate packaging of the finished product Change in shape or dimensions of the container or closure (immediate packaging)
•	12 April 2017	Submission of an updated Ph. Eur. certificate of suitability.
•	02 February 2016	Change in shape or dimensions of the container or closure (immediate packaging). Change in the specification parameters and/or limits of the immediate packaging of the finished product.
•	20 May 2015	Changes in the specification parameters of an excipient.

•	04 February 2015	Updates to the product literature.
•	16 December 2014	Submission of an updated Ph. Eur. Certificate of Suitability for the active substance.
•	10 March 2014	Change in the specification parameters of the finished product.
•	19 May 2011	Removal of a manufacturer of the active substance Submission of a new Ph. Eur. Certificate of Suitability for an active substance
•	23 June 2010	Addition of statement regarding mixing with other products onto Product Literature
•	03 December 2008	Change in test procedure performed on the finished product
•	06 August 2008	Change to legal category from PML to POM-VPS Changes to the SPC and Product Literature to bring in line with new legislation
•	14 December 2007	Change of name of a manufacturer of the active substance
•	13 February 2006	Renewal
•	21 May 2004	Change of distributor
•	29 January 2004	Renewal
•	27 January 2004	Change to manufacturing process of the finished product
•	14 March 2003	Changes to specification of the finished product
•	16 August 2002	Additional pack types – 1L, 2.5L and 5L backpacks
•	25 November 1998	Change of manufacturer of an active substance
•	17 February 1997	Change of formulation Change of product name from ‘Endospec 10%’ to ‘Endospec SC 10%w/v Oral Solution’