Veterinary Medicines Directorate

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Post Authorisation Assessments

Rycoben SC 2.50% w/v Oral Suspension for Sheep

•	19 May 2021	Change(s) in the SPC and Package Leaflet to implement the outcome of a procedure concerning PSUR.
•	08 April 2021	Replacement of a site where batch control/testing takes place. Minor change in the manufacturing process of the finished product.
•	16 October 2020	Change in the address of the Marketing Authorisation Holder from Elanco Europe Ltd, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL, United Kingdom to Elanco Europe Ltd, Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	06 July 2017	Change in the name and address of a manufacturer of the finished product, also responsible for batch release.
•	07 March 2017	Introduction of a new pharmacovigilance system.
•	12 May 2016	Addition of a new site of manufacturer of the active substance.
•	09 March 2016	Increase in batch size (including batch size range*) of the finished product.
•	15 December 2015	Change of MAH holder and Distributor from Novartis Animal Health UK Ltd to Elanco Europe Ltd.
•	12 December 2012	Minor changes to the manufacturing process of the finished product.
•	17 August 2011	Notification to add anthelmintic symbols to the packaging.
•	09 August 2010	Change in the name of the active substance manufacturer.
•	30 June 2010	Addition of the phrase' Do not mix with other products' to Section 4.9 of the SPC.
•	03 November 2009	Addition of an active substance manufacturer.
•	15 July 2009	Addition of a test to the finished product specification.
•	11 March 2009	Addition of a test to the finished product specification.
•	04 April 2008	Changes to the SPC and product literature to bring them into line with new legislation.
•	04 April 2008	Change of legal category from PML to POM-VPS.
•	12 October 2007	Change of MAH and distributor address.
•	12 September 2007	Removal of a test for identication of an excipient.
•	06 June 2007	Change in test procedure for an excipient.
•	16 October 2006	Renewal.

•	08 November 2005	Re-classification of excipients.
•	27 June 2003	Change of colour of primary packaging.
•	13 January 2003	Additional pack type.