Veterinary Medicines Directorate

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Post Authorisation Assessments

Ronaxan 100 mg Tablet for dogs and cats

Vm 08327/4068

•	12 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
•	05 July 2022	Changes to the labelling or the package leaflet which are not connected with the summary of product characteristics.
•	27 January 2021	Changes to the SPC/product labelling/package leaflet following an Article 34 referral.
•	28 May 2020	Change in the name and address of a manufacturer of the finished product, also responsible for batch release.
•	01 November 2018	Change in the name and address of the marketing authorisation holder from Merial Animal Health Ltd, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex, CM19 5TG to Boehringer Ingelheim Animal Health UK Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS.
•	19 November 2015	Submission of an updated certificate of suitability.
•	13 February 2014	Addition of a new therapeutic indication.
•	13 February 2014	Change in test procedure for the finished product. Changes in the specification parameters and/or limits of the finished product. Change in the batch size of the finished product. Change in the manufacturing process of the finished product. Change to in-process tests or limits applied during the manufacture of the finished product. Deletion of some excipients of the finished product.
•	19 October 2011	Change in the composition of the finished product.
•	19 October 2011	Change in test procedure for the finished product.
•	19 October 2011	Change in the manufacturing process of the finished product.
•	02 August 2011	Changes of batch size of the finished product.
•	11 July 2011	Registration of tests for in-process controls for the finished product.
•	11 July 2011	Minor changes to an approved test procedure.
•	11 July 2011	Deletion of an in-process test.
•	11 July 2011	Deletion of tests for the finished product.
•	11 July 2011	Submission of an EDQM certificate of suitability for an active substance manufacturer.
•	28 November 2007	Changes to the SPC and product literature to bring them into line with new legislation.

•	28 November 2007	Change in legal category from POM to POM-V.
•	06 January 2006	Renewal.
•	27 February 2003	Harmonisation of SPC.
•	30 May 2002	Renewal.
•	30 November 1998	Change of name of MAH.
•	14 November 1996	Renewal.
•	26 September 1995	Additional assemblers.