Veterinary Medicines Directorate

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Post Authorisation Assessments

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Vm 08327/4134

•	31 October 2023	Update to the description of starting materials of biological origin.
•	01 August 2023	Addition of a secondary packaging site of a finished product.
•	27 June2023	A modification to the active ingredient manufacturing process, to allow the use of cell dissociation enzyme of non-animal origin as an alternative to porcine trypsin.
•	06 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
•	04 July 2022	Correction of mistakes and editorial change in the description of the manufacturing process of active substance.
•	14 July 2021	Change in the specification parameters of the immediate packaging of the finished product.
•	19 March 2021	Minor changes to an approved test procedure of the finished product
•	15 February 2021	Deletion of manufacturing site for the finished product.
•	14 January 2021	Deletion of manufacturing site for an active substance.
•	26 November 2020	Change in the name of the manufacturer of the finished product.
•	10 November 2020	Change of a test procedure for the active substance.
•	14 August 2020	Changes in the manufacturing process of the finished product.
•	22 July 2020	Change in the name of a manufacturer of the active substance.
•	18 June 2020	Change in the name of the manufacturer of the finished product.
•	27 May 2020	Change in the name of a manufacturer of the finished product, also responsible for batch release.
•	29 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.
•	09 July 2018	Change in the name of a manufacturer of active substance used in the manufacture of the active substance.
•	31 October 2017	Replacement of a test procedure for the active substance.
•	17 October 2012	Variation to declare that an excipient used by Merial

		complies with the current European Pharmacopoeia: Monograph 1041, and to declare that the same excipient used if of vegetable origin as opposed to animal origin.
•	30 September 2010	Renewal.
•	26 November 2009	Addition of an alternative site for active substance manufacture.
•	04 August 2009	Renewal.
•	04 June 2009	Renewal.
•	04 June 2009	Renewal.
•	04 June 2009	Renewal.
•	25 June 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from POM to POM-V.
•	20 July 2007	Addition of a manufacturer.
•	28 December 2006	Renewal.
•	20 December 2005	Change to comply with the current European Pharmacopoeia.
•	29 April 2004	Renewal.
•	27 September 2002	Renewal.
•	27 September 2002	Renewal.
•	31 August 2000	Change to the active substance manufacture and addition of a site for QC testing.
•	27 July 2000	Renewal.
•	17 December 1999	Renewal.
•	04 March 1999	Change in the qualitative particulars.
•	09 October 1998	Change in the name of the ATC/PL Holder.
•	19 June 1998	Renewal.