Veterinary Medicines Directorate

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Post Authorisation Assessments

Phenoleptil 12.5 mg Tablets for Dogs

Vm 50406/4023

•	03 February 2023	Change in the immediate packaging of the finished product. Minor changes to the manufacturing process of the finished product. Change in the holding time of an intermediate or bulk product. Addition of manufacturing site where batch control and batch release of the finished product takes place. Change to in-process tests or limits applied during the manufacture of the finished product. Addition of a manufacturing site for the manufacture of the finished product. Addition of a manufacturing site for primary packaging of the finished product. Addition of a manufacturing site for secondary packaging of the finished product.
•	24 November 2022	Change in MAH from Le Vet B.V., Wilgenweg 7, 3421 TV Oudewater, The Netherlands to Dechra Regulatory B.V., Handelsweg 25, 5531 AE Bladel, The Netherlands.
•	06 May 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	05 November 2019	Introduction of a new pharmacovigilance system.
•	04 July 2019	Changes to the labelling and/or package leaflet. Change of distributor from Animalcare Ltd. to Dechra Veterinary Products Limited.
•	02 April 2019	Change in RMS from UK to IE.
•	17 January 2018	Replacement of components (excipients) of the flavouring or colouring system of the finished product.
•	29 June 2015	Replacement site of batch release.
•	25 June 2015	Submission of an updated certificate of suitability.
•	29 January 2015	Renewal – UK as RMS.
•	07 October 2013	Change in distributor details.
•	15 June 2011	Changes to veterinary medicinal products.
•	11 March 2011	Repeat Use Procedure.
•	16 June 2010	To change the address of the Marketing Authorisation Holder.