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Post Authorisation Assessments

Vidalta 15 mg Prolonged-release Tablets for Cats Vm 01708/4530

•	01 November 2023	Submission of an updated certificate of suitability. (NI)
•	11 January 2023	New certificate of suitability from an already approved manufacturer.
•	14 August 2020	Change in the name of the marketing authorisation holder from Intervet UK Limited to MSD Animal Health UK Limited.
•	13 November 2018	Change in the safety database of an existing pharmacovigilance system as described in the DDPS
•	28 March 2018	Addition of a 100 day in use shelf life.
•	12 March 2018	Change in RMS from UK to IE.
•	27 April 2017	Addition of a new specification parameter to the specification with its corresponding test method of the immediate packaging of the finished product. Deletion of a non-significant specification parameter of the immediate packaging of the finished product. Deletion of a non-significant specification parameter of the immediate packaging of the finished product. Deletion of a non-significant specification parameter of the immediate packaging of the finished product. Change in the specification parameters and limits of the finished product.
•	02 February 2017	Renewal – UK as RMS.
•	16 December 2016	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	04 December 2015	Change to comply with an update of the relevant monograph of the Ph. Eur.
•	04 December 2014	Update to the DDPS.
•	25 September 2014	Deletion of non-significant specification parameters of the immediate packaging of the finished product. Change to in-process control limits applied during the manufacture of the finished product. Change in the specification limits of the finished product. Change in test procedure for the immediate packaging of the finished product.
•	25 February 2014	Change of manufacturer of the active substance, minor change to the manufacturing process of the active and minor change to the approved test procedure.
•	14 February 2013	Change in the name of the manufacturing site of the active ingredient.
•	10 October 2012	Approval of joint labelling between UK and Ireland and approval of a distributor for Ireland

•	21 March 2012	To change the layout for labels and cartons.
•	12 January 2012	New MRP
•	14 December 2010	Update of Safety and Efficacy data.
•	14 July 2010	Evaluation of the storage conditions of the finished product prior to MRP.
•	14 April 2010	To add colour blocks to cartons and labels to differentiate between the two tablet strengths.
•	26 February 2010	Product specification.
•	14 May 2008	To make a change in the dessicant, which is placed in a plastic desiccant insert (inside the cap)