

## Post Authorisations Assessment

## Vidalta 10 mg Prolonged-release Tablets for Cats Vm 01708/4529

1	
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. 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.
16 December 2016	Renewal-UK as RMS 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.
	<ul> <li>11 January 2023</li> <li>14 August 2020</li> <li>13 November 2018</li> <li>28 March 2018</li> <li>12 March 2018</li> <li>27 April 2017</li> <li>02 February 2017</li> <li>16 December 2016</li> <li>04 December 2014</li> </ul>

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 2011	Update of Safety and Efficacy data.
14 July 2010	Assessment of shelf life.
21 April 2010	Correction/simple text layout changes to SPC and/or product literature.
26 February 2010	Product specification.
14 May 2008	Change in the qualitative and/or quantitative composition of the immediate packaging material.
	14 February 2013         10 October 2012         21 March 2012         12 January 2012         14 December 2011         14 July 2010         21 April 2010         26 February 2010