Veterinary Medicines Directorate

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Post Authorisation Assessments

Felimazole 5 mg Coated Tablets for Cats

Vm 10434/4061

•	01 September 2021	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product for solid pharmaceutical forms. Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product. Deletion of a non-significant parameter of an active substance used in the manufacturing process of the active substance. Deletion of a non-significant parameter of an active substance used in the manufacturing process of the active substance. Deletion of a non-significant specification parameter of an excipient. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Replacement to a test procedure for the finished product.
•	15 July 2020	Change in the specification limits of the finished product.
•	18 February 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	17 December 2019	Deletion of manufacturing site where batch control takes place for the finished product.
•	18 June 2019	Addition of a manufacturer responsible for batch release including batch control/testing.
•	12 April 2019	Deletion of manufacturing site for the finished product
•	12 February 2019	Changes to an existing pharmacovigilance system as described in the DDPS.
•	01 August 2018	Change in the RMS from UK to IE.
•	21 May 2018	Increase in the shelf-life of the finished product as packaged for sale, from 2 years to 3 years.
•	09 February 2018	Repeat Use application to add 5 new member states
•	25 October 2017	Addition of a new container for the finished product.
•	08 September 2016	Minor changes to an approved test procedure. Minor changes to an approved test procedure.

•	13 April 2016	Updated labels and package leaflet approved.
•	19 November 2015	Addition of a site where batch testing takes place.
•	19 July 2012	Grouped variation to amend the excipients of the tablet coating, amend the excipients, and increase the batch size.
•	07 March 2012	Significant changes to the SPC.
•	09 February 2012	Variation to change a test method used in the manufacturing process.
•	24 February 2011	Changes to an existing pharmacovigilance system as described in the DDPS.
•	15 December 2010	Change of distributor.
•	16 September 2010	Changes in the composition (excipients) of the finished product.
•	16 September 2010	Submission of a new/updated Ph. Eur Certificate of Suitability.
•	10 September 2010	Change in the shelf-life or storage conditions of the finished product.
•	25 June 2010	Renewal.
•	1 July 2009	Dosage instructions.
•	24 April 2009	Minor changes in manufacturing process of active.
•	30 September 2008	Change of Marketing Authorisation Holder.
•	19 October 2006	Correction/ simple text changes to SPC and /or product literature.
•	23 June 2006	Change of distributor.
•	26 May 2005	MRP.
•	04 July 2003	Change to the finished product shelf life.
•	17 December 2002	Change to the indications.