Veterinary Medicines Directorate

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Post Authorisation Assessments

Felimazole 2.5 mg Coated Tablets for Cats

Vm 10434/4050

19 February 2025	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance. (GB).
19 January 2025	Minor changes to an approved test procedure for the finished product (NI)
25 November 2024	Minor changes to an approved test procedure for the finished product.(GB)
16 October 2024	Deletion of a non-significant specification parameter in the specification parameters or limits of an excipient.
10 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. 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. Change of specification(s) of a former non Pharmacopoeial excipient to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State. Change in components (excipients) of the flavouring or colouring system of the finished product. Replacement to a test procedure for the finished product.
17 March 2020	Addition of a specification parameter with its corresponding test method of the finished product.
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 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.
13 April 2016	Updated labels and package leaflet approved.
10 December 2015	Additional sites where batch testing takes place for the finished product.
30 March 2015	Renewal – UK as RMS.
07 March 2012	Significant changes to the SPC and Package Leaflet.
09 February 2012	Change in the finished product test procedure.
24 February 2011	Changes to an existing pharmacovigilance system as described in the DDPS.
15 December 2010	Change of Distributor.
01 October 2010	Changes (Safety/Efficacy) to human and veterinary medicinal products.
16 September 2010	Changes in the composition of the excipients of the finished product.
16 September 2010	Submission of a new/updated Ph. Eur Certificate of Suitability.
09 May 2008	Change of Marketing Authorisation Holder.
19 December 2007	Change in the shelf-life of the finished product.
02 November 2007	Minor change in the manufacturing process of the active substance.
15 August 2006	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
23 June 2006	Change of distributor.
23 November 2005	Change in batch size of finished product.