Veterinary Medicines Directorate

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Post Authorisation Assessments

Felimazole 1.25 mg Coated Tablets for Cats

Vm 10434/4082

15 April 2025	Change to quality testing arrangements for a finished product. (GB)
19 March 2025	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance. (NI)
19 February 2025	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance. (GB).
09 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 specification parameter of an excipient. Replacement to a test procedure for the finished product.
15 July 2020	Change in the specification limits of the finished product.
17 December 2019	Deletion of manufacturing site where batch control takes place for the finished product.
12 November 2019	Minor change in the manufacturing process of the finished product.
25 September 2019	Repeat Use application to add 10 new member states.
18 June 2019	Addition of a manufacturer responsible for batch release including batch control/testing.
12 April 2019	Deletion of manufacturing site of the finished product
12 February 2019	Changes to an existing pharmacovigilance system as described in the DDPS.
23 November 2018	Renewal - UK as RMS.
15 November 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.
02 May 2018	Update to section 5.2 of the SPC.
20 December 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
25 October 2017	Addition of a new container for the finished product.
27 April 2017	Increase in the shelf-life of the finished product as packaged for sale, from 18 months to 36 months.

08 September 2016	Minor changes to an approved test procedure.
13 April 2016	Updated labels and package leaflet approved.
13 November 2015	Addition of a site where batch testing takes place. Addition of a site where batch testing takes place.