Veterinary Medicines Directorate

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# Post Authorisation Assessments

## Felimazole 2.5 mg Coated Tablets for Cats

Vm 10434/4050

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| • | 10 September 2021 | Changes in the qualitative and quantitative composition of the immediate packaging of the finished product for solid pharmaceutical forms.<br>Minor changes to an approved test procedure of the finished product.<br>Minor changes to an approved test procedure of the finished product.<br>Minor changes to an approved test procedure of the finished product.<br>Minor changes to an approved test procedure of the finished product.<br>Deletion of a non-significant parameter of an active substance used in the manufacturing process of the active substance.<br>Deletion of a non-significant parameter of an active substance used in the manufacturing process of the active substance.<br>Deletion of a non-significant specification parameter of an excipient.<br>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.<br>Change in components (excipients) of the flavouring or colouring system of the finished product.<br>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. |

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| • | 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. |