



Post Authorisation Assessments

Felimazole 5 mg Coated Tablets for Cats

•	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.