Veterinary Medicines Directorate

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Post Authorisation Assessments

Nisamox Palatable Tablets 500 mg for Dogs

•	15 February 2022	Deletion of a non-significant specification parameter of an excipient.
•	10 December 2019	Addition of a secondary packaging site of the finished product. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	30 July 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	03 June 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	11 January 2019	Change in RMS from UK to ES.
•	04 January 2019	Update of the test procedure to comply with the updated general Ph. Eur monograph. Changes to a test procedure for the finished product.
•	28 December 2017	Change in distributor details from Bayer plc, Animal Health, Strawberry Hill, Newbury, RG14 1JA to Bayer plc, 400 South Oak Way, Green Park, Reading, RG2 6AD.
•	31 March 2016	Submission of new or updated Ph. Eur. certificates of suitability Deletion of Ph. Eur. certificates of suitability
•	28 November 2014	Update to the DDPS.
•	07 March 2013	Submission of updated Ph. Eur. Certificates of Suitability for already approved manufacturers. Deletion of an active ingredient manufacturing site.
•	28 December 2011	Renewal – UK as RMS.
•	10 November 2010	Change of distributor.
•	23 October 2008	New/updated Ph. Eur. Certificate of Suitability for active/active component new manufacturer/other.