Veterinary Medicines Directorate

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Post Authorisation Assessments

Nisamox 250 mg Tablets 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.
•	29 November 2019	Minor change in the manufacturing process of an immediate release solid oral dosage form. Qualitative / quantitative changes to the excipients.
•	03 June 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	14 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.
•	23 March 2016	Submission of a new or updated Ph. Eur. certificate of suitability Submission of a new or updated Ph. Eur. certificate of suitability Submission of a new or updated Ph. Eur. certificate of suitability Deletion of a Ph. Eur. certificate of suitability Deletion of a Ph. Eur. certificate of suitability Submission of a new or updated Ph. Eur. certificate of suitability
•	28 November 2014	Update to the DDPS.
•	03 January 2014	Submission of updated Ph. Eur. Certificates of Suitability for an already approved manufacturer.
•	24 November 2011	Changes to SPC section 2 and appropriate sections of the Product Literature.
•	03 June 2011	Change of product name in Italy only.
•	27 April 2011	Removal of a manufacturer of the active substance.
•	10 November 2010	Change of distributor.
•	05 August 2009	Renewal.

•	25 April 2008	Change of shelf life from 18 months to 24 months.
•	09 April 2008	Change of composition of immediate packaging.
•	17 April 2007	Change of legal category from POM to POM-V. Addition of a manufacturer of the active substance.
•	20 February 2007	Updates to the Product Literature.
•	28 October 2005	Change of shelf life from 1 year to 18 months.
•	15 November 2004	Mutual Recognition Procedure, UK as RMS.
•	16 May 2003	Additional presentation.