Veterinary Medicines Directorate

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Post Authorisation Assessments

Synulox Palatable Tablets 250 mg

Vm 42058/4145

•	17 January 2023	Deletion of obsolete batch sizes of the finished product.
•	04 March 2022	Changes in the SPC, Labelling or Package Leaflet intended to implement the outcome of a PSUR.
•	15 December 2021	Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	27 August 2020	Change in the address of the marketing authorisation holder from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP.
•	10 September 2019	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. Introduction of a storage period of the active substance.
•	07 September 2018	Deletion of Ph. Eur. certificates of suitability for an active substance. Deletion of Ph. Eur. certificates of suitability for an active substance. Submission of a new Ph. Eur. certificate of suitability for an active substance. Submission of a new Ph. Eur. certificate of suitability for an active substance. Submission of a new Ph. Eur. certificate of suitability for an active substance. Submission of a new Ph. Eur. certificate of suitability for an active substance. Introduction of a re-test period of the active substance. Introduction of a re-test period of the active substance.
•	September 2017	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. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	26 June 2014	To change the Marketing Authorisation Holder and

		distributor.
•	22 July 2009	Variation to change the name of the finished product manufacturer, as well as the name of the active substance manufacturer.
•	06 February 2009	Variation to submit a new European Pharmacopoeia Certificate of Suitability for an active substance manufacturer.
•	06 February 2009	Variation to submit a new European Pharmacopoeia Certificate of Suitability for an active substance manufacturer.
•	22 January 2009	Submission of a Variation to submit a new European Pharmacopoeia Certificate of Suitability for a new active substance manufacturer.
•	13 February 2008	Addition of a batch size.
•	20 July 2007	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from POM to POM-V.
•	08 June 2006	Renewal.
•	28 July 2005	Variation to change the site of a manufacturing process of the active substance.
•	17 June 2005	Addition of a distributor.
•	26 September 2003	Renewal.
•	27 February 2003	Change of name of the dosage form assembler.
•	28 June 2001	Change in the manufacturing process of the active substance.
•	11 August 2000	Variation concerning the active substance manufacturer.
•	26 May 1997	QC Procedure.