



## **Post Authorisation Assessments**

### **Synulox Palatable Drops, Powder for Oral Suspension**

Vm 42058/4144

•	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.
•	25 November 2021	Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product.
•	24 November 2021	Change in shape or dimensions of the container or closure (immediate packaging).
•	27 April 2021	Update of the quality dossier intended to implement the outcome of a Union referral procedure.
•	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, 1 <sup>st</sup> Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP.
•	17 February 2020	Change in shape or dimensions of the container or closure (immediate packaging).
•	15 July 2019	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new 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.
•	15 May 2018	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. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Deletion of Ph. Eur. certificates of suitability for an active substance. Introduction* of a re-test period of the active substance.

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•	26 June 2014	To change the Marketing Authorisation Holder and distributor.
•	14 September 2011	Change in the immediate packaging of the finished product.
•	22 July 2009	Grouped variation to change the name of a finished product manufacturer, as well as the name of an active substance manufacturer.
•	26 March 2009	Submission of a new European Pharmacopoeia Certificate of Suitability.
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•	22 January 2009	Submission of a new European Pharmacopoeia Certificate of Suitability for a new active substance manufacturer.
•	13 February 2008	Variation to include an additional size of batch release.
•	20 June 2007	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from POM to POM-V.
•	31 July 2006	Renewal.
•	28 July 2005	Variation to change the site of a manufacturing process of the active substance.
•	27 June 2005	Addition of a distributor.
•	01 August 2003	Renewal.
•	27 February 2003	Change of the name of the assembler for dosage form.
•	31 October 2001	Change to the dimensions of the non-sterile containers.
•	28 June 2001	Change in the manufacturing process of the active substance.
•	05 November 1996	Change of legal entity.
•	17 September 1996	Renewal.