Veterinary Medicines Directorate

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Post Authorisation Assessments

Synulox Ready-To-Use Suspension for Injection

Vm 42058/4148

•	04 March 2022	Changes in the SPC, Labelling or Package Leaflet intended to implement the outcome of a PSUR.
•	25 November 2021	Submission of a new certificate of suitability for an active substance.
•	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.
•	23 October 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.
•	13 January 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. Addition of an alternative sterilisation site for the active substance.
•	26 June 2014	To change the Marketing Authorisation Holder and distributor.
•	22 July 2009	Variation to change the name of the finished product and active substance manufacturer.
•	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.
•	09 January 2007	Renewal.
•	25 October 2005	Addition of a site of micronisation of the active substance.
•	23 June 2005	Addition of a distributor.
•	04 March 2004	Renewal.
•	04 March 2003	Variation to change the name of the assembler of dosage form.
•	07 December 2001	Changes to the SPC.
•	19 October 2001	Changes to a withdrawal period (pigs).
•	19 October 2001	Changes to a withdrawal period (cattle).

•	28 June 2001	Change in the manufacturing process of the active substance.
•	25 January 2000	Renewal.
•	27 February 1997	Change of manufacturer of the bulk and finished product.
•	18 December 1996	Change of Marketing Authorisation Holder.