Veterinary Medicines Directorate

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Post Authorisation Assessments

Synulox Lactating Cow Intramammary Suspension

Vm 42058/5105

•	27 February 2024	One-off alignment of the product information with version 9.0* of the QRD template.
•	25 October 2022	Change in the batch size of the finished product.
•	29 October 2021	Submission of a new certificate of suitability for an active substance.
•	03 December 2020	Deletion of manufacturing site for an active substance. Deletion of Ph. Eur. certificates of suitability for an active substance. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	03 December 2019	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.
•	01 March 2019	Change in RMS from UK to IE.
•	27 February 2019	Harmonisation of the quality dossier in all Member States as a result of a referral procedure – product is now mutually recognised.
•	06 October 2017	Deletion of a manufacturing site of the dosage form. Submission of an updated Ph. Eur. certificate of suitability for an active substance manufacturer.
•	23 January 2017	Change in the name of a site used in the manufacture of the active substance. Change in the name and address of a site used in the manufacture of the active substance. Submission of an updated Ph. Eur. certificate of suitability from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability from an already approved manufacturer. Addition of an alternative sterilisation site for the active substance. Addition of an alternative sterilisation site for the active substance. Submission of a new certificate of suitability.
•	15 May 2015	Addition of a specification parameter.
•	26 June 2014	To change the Marketing Authorisation Holder and distributor.
•	08 January 2014	Variation to update the SPC and packaging following completion of the EU Article 34 referral for the product.

•	22 July 2009	Grouped variation to change the name of the finished product manufacturer, as well as the active substance manufacturer.
•	22 January 2009	Submission of a new Certificate of Suitability for the addition of an active substance manufacturer.
•	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.
•	07 June 2006	Renewal.
•	28 July 2005	Variation to change the site of a manufacture process for the active substance.
•	30 June 2005	Addition of a distributor.
•	16 January 2004	Renewal.
•	17 July 2003	Renewal.
•	27 February 2003	Variation to change the name of a dosage form assembler.
•	05 December 2001	Corrections to the SPC.
•	17 July 2001	Change to the active substance manufacturer.
•	28 June 2001	Change in the manufacturing process of the active substance.
•	31 August 1999	Renewal.
•	23 September 1997	Addition of a pack size.
•	09 April 1997	Addition of a manufacturer responsible for dosage form and assembly.
•	27 February 1997	Change of Marketing Authorisation Holder.
•	31 May 1996	Addition of an assembler.