Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

# Post Authorisation Assessments

## Synulox Lactating Cow Intramammary Suspension

Vm 60021/3038

| | |
|---|---|
| 10 March 2025 | Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).<br>Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. |
| 14 January 2025 | Change of MAH from: Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP to Zoetis Belgium S.A., 2nd Floor, Building 10, Cherrywood Business Park, Loughlinstown, Dublin 18, D18 T3Y1, Ireland. |
| 14 January 2025 | Change in the manufacturer of an active substance where no Ph. Eur. certificate of suitability is part of the approved dossier.<br>Submission of a new CEP for the manufacture of an active substance. |
| 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.<br>Deletion of Ph. Eur. certificates of suitability for an active substance.<br>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 |
| 06 October 2017 | Deletion of a manufacturing site of the dosage form.<br>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.<br>Change in the name and address of a site used in the manufacture of the active substance.<br>Submission of an updated Ph. Eur. certificate of suitability from an already approved manufacturer.<br>Submission of an updated Ph. Eur. certificate of suitability from an already approved manufacturer.<br>Addition of an alternative sterilisation site for the active substance.<br>Addition of an alternative sterilisation site for the active substance.<br>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. |