Veterinary Medicines Directorate

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# Post Authorisation Assessments

## Stellamune Once Emulsion for Injection

Vm 52127/3081

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| 09 February 2026 | Addition of a new 20 mm grey rubber stopper. |
| 14 January 2026 | Approval of mock-ups. |
| 10 November 2025 | Change of legal entity of the Marketing Authorisation Holder from Elanco Europe Ltd, Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA United Kingdom to Elanco GmbH, Heinz-Lohmann Strasse 4, Groden, 27472 Cuxhaven, Germany. |
| 17 October 2025 | One-off alignment of the product information with version 9.0 of the QRD templates. |
| 09 January 2025 | Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV) (NI).<br>Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex (NI). |
| 01 December 2024 | Change in the address of a manufacturer of the finished product.<br>Change in the address of the manufacturer of the active substance.<br>Deletion of a manufacturing site for an active substance, packaging site and manufacturer responsible for batch release.<br>Deletion of a pack size that does not lead to the complete deletion of a strength. |
| 02 March 2022 | Change in Distributor from Pfizer Ltd, Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom and UniDrug Distribution Group Ltd., Amber Park, Berristow Lane, South Normanton, Alfreton, Derbyshire, DE55 2HF, United Kingdom to Elanco UK AH Ltd, Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom. |
| 19 January 2021 | Change of MAH, from Eli Lilly and Company Limited, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL to Elanco Europe Ltd., Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom. |
| 14 July 2020 | Tightening of specification limits of an active substance used in the manufacturing process of the active substance.<br>Deletion of a non-significant in-process test applied during the manufacture of the finished product.<br>Addition of a secondary packaging site of the finished product.<br>Change in the manufacturer of the active.<br>Addition of a site where batch control/testing takes place.<br>Addition of a manufacturing site of the finished product. |
| 05 June 2019 | Change in the safety database of an existing pharmacovigilance system as described in the DDPS. |
| 17 May 2018 | Change in RMS from UK to DE. |

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| 16 January 2015 | Addition of a site for part of the manufacturing process, QC testing and batch release. |
| 31 October 2014 | Change to the specification of a starting material used in the manufacturing process of the active substance. |
| 24 April 2014 | Reduction of recommend age of vaccination from 7 days to 3 days of age and extension of the duration of immunity in piglets from at least 25 weeks to 26 weeks following vaccination. |
| 03 April 2014 | Changes to an existing pharmacovigilance system. |
| 07 November 2013 | Variation to change the registered address of the Marketing Authorisation Holder in PT. |
| 29 September 2013 | Renewal in new CMS (BG and RO). |
| 13 June 2013 | Variation to change the Marketing Authorisation Holder in France only. |
| 18 May 2012 | Variation to make minor amendments to the wording of the SPC and PL. |
| 16 December 2011 | Variation to change the address of the Marketing Authorisation Holder in DK, IS, NO, and SE only. |
| 06 July 2011 | Variation to make minor layout changes to the label. |
| 14 December 2010 | Variation to change the Marketing Authorisation Holder. |
| 09 December 2009 | Variation to remove and target species and a batch safety test. |
| 06 August 2009 | Variation to change the product name in Romania and Bulgaria only. |
| 04 November 2008 | MRP – UK as RMS |
| 21 August 2008 | Addition of an alternative non-ruminant PPLO broth. |
| 26 June 2008 | Variaiton to update the product packaging. |
| 04 October 2007 | Renewal. |
| 09 November 2006 | Addition of an alternative source of an excipient. |
| 19 October 2005 | Change to the ‘Indiciations’ section of the SPC. |
| 27 June 2005 | Variation to change the distributor. |
| 26 May 2005 | Extension of the shelf life of the finished product. |
| 26 March 2004 | Repeat Use. |
| 09 October 2003 | Changes to the minimum age for vaccination. |
| 28 January 2003 | Extension of the shelf life of the finished product. |
| 06 September 2002 | MRP – UK as RMS. |