Veterinary Medicines Directorate

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Post Authorisation Assessments

Stellamune Once
Vm 00879/4202

•	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. Deletion of a non-significant in-process test applied during the manufacture of the finished product. Addition of a secondary packaging site of the finished product. Change in the manufacturer of the active. Addition of a site where batch control/testing takes place. 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.
•	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.