Veterinary Medicines Directorate

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

Post Authorisation Assessments

Program 80 mg Suspension for Injection

Vm 00879/4038

•	11 May 2024	Change to comply with an update of the relevant monograph of the Ph. Eur..
•	22 October 2020	Change in the address of the Marketing Authorisation Holder from Elanco Europe Ltd, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL, United Kingdom to Elanco Europe Ltd, Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom.
•	31 January 2020	Minor change in the manufacturing process of the finished product. Deletion of a non-significant specification parameter of the finished product. Replacement of a site where batch control/testing takes place. Addition of new tests and limits applied during the manufacture of the finished product. Deletion of a non-significant in-process test applied during the manufacture of the finished product. Replacement of a secondary packaging site of the finished product. Changes to a test procedure for the finished product. Harmonisation of the SPC & QRD texts. Change in type of container for the finished product. Change in the specification limits of the finished product.
•	26 September 2019	Change in the address of a manufacturer used in the manufacture of the active substance.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	24 January 2019	Change in the address of a manufacturer used in the manufacture of the active substance.
•	25 October 2017	Minor change in the manufacturing process of the finished product.
•	18 October 2017	Minor changes to an approved test procedure of the finished product. Minor change in the manufacturing process of the finished product. Minor change in the manufacturing process of the finished product. Minor change in the manufacturing process of the finished product. Change to the performance of the in-process test for fill volume.

		Replacement of a manufacturing site of the finished product.
•	07 March 2017	Introduction of a new pharmacovigilance system.
•	16 March 2016	Change in distributor details Change in legal entity
•	21 August 2015	Minor change in an already approved test procedure, and an update in test procedure to comply with the updated monograph in the Ph. Eur.
•	20 May 2015	Tightening of specification parameters for the active substance. Addition of a new in-process test applied during the manufacture of the active substance.
•	16 January 2015	Change in test procedure for the finished product.
•	12 September 2013	Grouped variation to change the test procedures and the specification parameters/ limits for the excipients.
•	12 July 2011	Variation to change the specifications to comply with the European Pharmacopoeia.
•	18 August 2010	Variation to change the name and contact details of the QPPV.
•	21 July 2010	Variation to change the name of the manufacturer responsible for manufacture, packaging, control and batch release.
•	19 September 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from POM to POM-V.
•	11 September 2008	Variation to change the name and or address of the finished product Manufacturer.
•	18 March 2008	Variatin to change the Marketing Authorisation Holder and Distributor Address.
•	05 July 2007	Renewal.
•	26 April 2006	Batch Control.
•	09 September 2004	Variation to change the site of manufacture and micronisation of the Active Substance.
•	16 April 2003	Renewal.
•	02 September 1998	Change to Safety Warnings.