Veterinary Medicines Directorate

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Post Authorisation Assessments

Program Tablets 67.8 mg

Vm 00879/4018

•	16 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.
•	01 November 2019	Change in the address of a manufacturer used in the manufacture of the active substance.
•	01 July 2019	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. Minor change in the manufacturing process of the finished product. Addition of new tests and limits applied during the manufacture of the finished product. Addition of new tests and limits applied during the manufacture of the finished product. Addition of new tests and limits applied during the manufacture of the finished product. Addition of new tests and limits applied during the manufacture of the finished product. 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. Deletion of a non-significant in-process test applied during the manufacture of the finished product. Deletion of a non-significant in-process test applied during the manufacture of the finished product. Deletion of a non-significant in-process test applied during the manufacture of the finished product. Change to in-process tests or limits applied during the manufacture of the finished product - complying with Ph. Eur.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.

•	21 January 2019	Change in the address of a manufacturer used in the manufacture of the active substance.
•	07 March 2017	Introduction of a new pharmacovigilance system.
•	10 August 2016	Change in the name of a manufacturer of the finished product including manufacturer responsible for batch release
•	13 January 2016	Change of Marketing Authorisation Holder from Novartis Animal Health UK Ltd to Elanco Europe Ltd. Change in distributor details.
•	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.
•	12 March 2015	Change in test procedure for an excipient.
•	12 July 2011	Variation to change the active substance specifications from in-house specifications to specifications as defined in the current edition of the Ph. Eur. Monograph.
•	30 April 2004	Variation to bring the SPC/Labelling in line with the Veterinary Regulations. 2005.
•	28 December 2007	Variation to change the address of the Marketing Authorisation Holder and distributor.
•	28 March 2007	Change of legal category from POM to AVM-GSL.
•	09 March 2005	Addition of a pack size (finished product).
•	03 December 2004	Change to testing instructions.
•	09 September 2004	Change in the sites of manufacture and micronisation of the active ingredient.
•	30 July 2004	Change of Marketing Authorisation Holder.
•	12 March 2004	Renewal.
•	11 September 1998	Renewal.
•	16 October 1997	Shelf life extension.
•	29 August 1997	Change of manufacturer and assembler of dosage form.
•	08 May 1997	Variation concerning QP Procedure.
•	30 April 1997	Change of company name.
•	17 June 1996	Change to the ‘Indications for use’.
•	07 July 1995	Change to the address of the assembler.