Veterinary Medicines Directorate

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Post Authorisation Assessments

Program Tablets 204.9 mg

Vm 00879/4019

•	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.
•	15 December 2016	Update to Section 4.9 of the SPC.
•	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	Change to the specifications of an active component from in-house specifications to specifications as defined in the current edition of the Ph. Eur. Monograph.
•	30 April 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	15 January 2008	Renewal.
•	28 December 2007	Change to the name and/or address of the Marketing Authorisation Holder.
•	28 March 2007	Change in the legal category from POM to AVM-GSL.
•	09 March 2005	Variation to include an additional pack size (finished product).
•	03 December 2004	Revised FPS.
•	09 September 2004	Change in the site of manufacture and micronisation of the active ingredient.
•	30 July 2004	Change to the Marketing Authorisation Holder address.
•	11 March 2004	Renewal.
•	16 December 1998	Renewal.
•	20 October 1997	Shelf-life extension.
•	29 August 1997	Change of manufacturer and assembler of dosage form.
•	08 May 1997	Variation concerning the QC Procedure.
•	30 April 1997	Change of company name.
•	17 June 1996	Change to ‘Indications for use’.
•	07 July 1995	Change to the address of an assembler. **Program Tablets 204.9mg**