Veterinary Medicines Directorate

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

Post Authorisation Assessments

Program Oral Suspension for Large Cats 266 mg

•	04 November 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.
•	23 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 July 2011	Change to comply with the European Pharmacopoeia.
•	09 July 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	18 March 2008	Variation to change the address of the Marketing Authorisation Holder.
•	28 March 2007	Variation to change the legal category from POM to AVM-GSL.
•	11 May 2006	Renewal.
•	29 November 2005	Increase the batch size of the finished product.
•	30 March 2005	Additional pack size (product).
•	03 September 2004	Change in the site of manufacture and micronisation of the Active Substance.
•	09 August 2002	Change of shelf-life of the finished product.
•	29 June 2001	Renewal.
•	17 July 1998	Addition of a Manufacturer (Bulk Suspension only).
•	19 May 1997	Assessment of by-product.
•	19 May 1997	Change of Marketing Authorisation Holder.
•	18 June 1996	Variation concerning an additional treatment.