Veterinary Medicines Directorate

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Post Authorisation Assessments

Program Oral Suspension for Small Cats and Kittens 133 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	Variation to change the specifications to comply with the European Pharmacopoeia.
•	09 July 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	15 January 2008	Renewal.
•	28 December 2007	Change to the address of the Marketing Authorisation Holder and Distributor.
•	28 March 2007	Change of legal category from POM to AVM-GSL.
•	24 November 2005	Variation to change the batch size.
•	31 March 2005	Variation to add an additional pack size.
•	03 September 2004	Change in the site of manufacture and micronisation of the Active Ingredient.
•	22 April 2004	Renewal.
•	14 August 2002	Extension of product shelf life.
•	05 October 1998	Renewal.
•	17 July 1998	Change of Manufacturer of Dosage Form (bulk solution only).
•	08 May 1997	By-product.
•	30 April 1997	Change of company name.
•	17 June 1996	Additional treatment.
•	12 February 1996	Varation concerning a change of trading style.

•	05 June 1995	Variation concerning a minor alteration to the Labelling/PL text.