Veterinary Medicines Directorate

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Post Authorisation Assessments

Program 40 mg Suspension for Injection for Cats

•	19 March 2018	Change in RMS from UK to ES.
•	24 November 2017	Minor change in the manufacturing process of the finished product.
•	26 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 in-process tests or limits applied during the manufacture of the finished product. Replacement of a manufacturing site of the finished product.
•	07 March 2017	Introduction of a new pharmacovigilance system.
•	21 June 2016	Change in the name and address of the Marketing Authorisation Holder from Novartis Animal Health S.p.A to Elanco Italia S.p.A. in Italy only, and from Novartis Sanidad Animal, S.L. to Elanco Spain, S.L.U. in Spain only.
•	16 March 2016	Change in distributor details Change in legal entity
•	30 June 2015	Tightening of specification limits of the active substance. Addition of a new in-process test and limits for the active substance.
•	13 February 2015	Change in test procedure for the finished product in line with Ph. Eur.
•	27 March 2014	Changes to an existing pharmacovigilance system.
•	16 January 2014	Change to the MAH address.
•	05 September 2013	Update of test procedure in line with Ph. Eur.
•	05 April 2013	Minor changes to an existing pharmacovigilance system as described in the DDPS.
•	28 March 2013	Change in name and/or address of MAH.
•	18 August 2011	Change in the specification of the active substance.
•	26 August 2010	Change in the name of a manufacturer and change in the name and details of the EU qualified person for pharmacovigilance.
•	14 October 2008	Change in the name of the finished product manufacturer.
•	02 September 2008	Renewal.

•	18 March 2008	Change of address of MAH and distributor.
•	19 January 2006	Minor change in the manufacture of the finished product.
•	06 August 2004	Change of manufacturer of the active substance.
•	27 November 2003	Renewal.
•	21 November 2000	Extension of shelf life.