Veterinary Medicines Directorate

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Post Authorisation Assessments

Program Plus Film-coated Tablets 5.75 mg/115 mg

•	13 September 2021	Reduction of the shelf life of the finished product as packaged for sale from 5 years to 3 years.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	20 February 2019	Change in the address of a manufacturer used in the manufacture of the active substance.
•	28 January 2019	Minor change in the manufacturing process of an immediate release solid oral dosage form.
•	09 November 2018	Change of specifications of a former non Pharmacopoeial active substance to comply with the Ph. Eur.
•	25 September 2017	Increase in batch size of the active substance. Change in the specification parameters and/or limits of a starting material used in the manufacturing process of the active substance.
•	07 March 2017	Introduction of a new pharmacovigilance system.
•	02 December 2016	Tightening of specification limits of the active substance. Addition of a new in-process test and limits for the active substance.
•	15 August 2016	Change in the name of a manufacturer of the finished product including manufacturer responsible for batch release
•	16 May 2016	Variation to change the marketing authorisation holders in both Spain and Italy.
•	13 January 2016	Change of Marketing Authorisation Holder from Novartis Animal Health UK Ltd to Elanco Europe Ltd. Change in distributor details.
•	28 April 2014	Grouped variation to change the Qualified Person for Pharmacovigilance (QPPV) and the QPPV contact details, as well as other changes to the existing pharmacovigilance systems as described in the DDPS.
•	10 February 2014	Change to the MAH address.
•	20 January 2014	Changes to the specification parameters and limits for the active substances and the finished product.
•	16 April 2013	Variation to make minor changes to an existing pharmacovigilance system as described in the DDPS.
•	31 December 2012	Change in the name of the veterinary medicinal product in Italy only.
•	13 September 2011	Change in the specifications of the former non Pharmacopoeial substance.
•	09 December 2010	Grouped variation to change the name and qualified details of the QP for Pharmacovigilance.

•	30 October 2009	EU Renewal, UK as CMS.
•	19 March 2009	Variation to replace the source of an active component.
•	22 October 2008	Deletion of an obsolete manufacturer.
•	20 October 2008	Change in the name of an active substance manufacturer.
•	01 May 2008	Change to the address of a Distributor.
•	30 June 2006	Change in the name of the veterinary medicinal product in Spain only.
•	08 November 2005	Extension of shelf life.
•	08 November 2005	Change in the name of the veterinary medicinal product in Spain and Austria.
•	19 October 2005	Change of ATC Code.
•	15 February 2005	Tightening of specifications of an active component.
•	15 February 2005	Change of address of an active ingredient manufacturer.
•	15 February 2005	Change of source of an active ingredient.
•	09 November 2004	Changes to an active substance manufacturer.
•	08 September 2004	Changes to the finished product specification.
•	24 June 2004	Addition of a finished product manufacturer.
•	14 January 2004	EUDE Renewal.
•	20 February 2002	QC Procedure.