Veterinary Medicines Directorate

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Post Authorisation Assessments

ACP Tablets 10 mg

Vm 00879/4011

•	25 September 2020	Change in the address of the MAH 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.
•	02 June 2020	Change in specification parameter of the finished product.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	07 March 2017	Introduction of a new pharmacovigilance system.
•	13 January 2016	Change of Marketing Authorisation Holder from Novartis Animal Health UK Ltd to Elanco Europe Ltd. Change in distributor details.
•	05 March 2015	Changes to section 4.10 of the SPC and corresponding sections of the product literature.
•	06 June 2014	Deletion of a finished product manufacturing site.
•	18 September 2013	Grouped variation to change the finished product batch size, change the importer, batch release arrangements, and quality control testing of the finished product, delete a manufacturer, and the addition of a manufacturer for part or all of the finished product manufacture process.
•	15 February 2013	Change in supplier of part of the packaging.
•	21 July 2010	Variation to make a minor change in the manufacture of the finished product.
•	24 October 2008	Addition of a site for batch release and testing.
•	27 June 2008	Variation to bring the SPC and labels in line with the new legislation and to transfer the legal category from POM to POM-V.
•	17 June 2008	Addition of a manufacturer of the active substance.
•	18 March 2008	Addition of an assembler of dosage form.
•	01 February 2008	Change in address of MAH.
•	11 January 2007	Renewal.
•	17 July 2003	Renewal.
•	12 August 2002	Change of name and address of the MA/ATC Holder.
•	24 July 1997	Transfer.
•	02 June 1997	Update of licence particulars.