



Post Authorisation Assessments

ACP Injection 10 mg/ml Solution for Injection

•	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.
•	17 October 2014	Change to the text in section 4.11 of the SPC and product literature.
•	25 June 2008	Variation to bring the SPC and labels in line with new legislation and to transfer the legal category from POM to POM-V.
•	17 June 2008	Addition of a manufacturer of the active substance.
•	30 January 2008	Change of MAH and Distributor address.
•	12 December 2006	Renewal.
•	29 November 2005	Changes to section 5.2 of the SPC 'Indications for Use'.
•	11 February 2004	Batch Control.
•	16 May 2003	Renewal.
•	09 May 2003	Assessment of Benzene according to VICH Guideline.
•	16 August 2002	Change of MAH from Grampian Pharmaceuticals to Novartis Animal Health UK Ltd.
•	15 December 1997	QC Procedures.
•	30 June 1997	Renewal.
•	17 June 1997	Change of manufacturer of dosage form.
•	14 June 1996	Variation to amend the labelling.