



Post Authorisation Assessments

Strongid-P Paste 43.90% w/w Vm 00879/4176

•	11 November 2022	Change(s) in the SPC, labelling or package leaflet to section 4.6 and 4.8.
•	28 February 2022	Change in distributors from Elanco Europe Ltd and UniDrug Distribution Group Ltd. to Elanco Europe Ltd. Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, UK.
•	01 October 2020	Change of Marketing Authorisation Holder from Eli Lilly and Company Limited, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL to Elanco Europe Ltd, Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	10 September 2014	Variation to align the wording on the packaging with that in the SPC.
•	23 May 2013	Addition of an alternative site for all of the manufacturing process of the finished product.
•	08 March 2011	Variation to change the Marketing Authorisation Holder.
•	07 July 2010	Variation to delete an active substance manufacturer.
•	23 June 2009	Addition of a manufacturing site for all of the manufacturing processes.
•	15 January 2009	Addition of an active substance manufacturer.
•	09 April 2008	Variation to update the Special Warnings on the SPC and subsequently the Package Leaflet.
•	09 August 2007	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from PML to POM-VPS.
•	25 April 2007	Change in the active substance manufacturer.
•	07 September 2006	Variation to remove the tertiary contained from the Marketing Authorisation.
•	08 August 2006	Variation to change the batch release arrangements.
•	06 December 2005	Minor modification to an approved FPS test method.
•	29 November 2005	Renewal.
•	27 September 2005	Change in the formulation of the finished product.
•	15 September 2005	Change in the specifications of the active

		substance/
•	24 June 2005	Addition of a distributor.
•	10 June 2005	Variation to extend the product withdrawal period.
•	19 November 2004	Change in the qualitative composition of the immediate packaging material.
•	16 July 2004	Change in the composition of the immediate packaging material.
•	02 November 2001	QC Procedures.
•	20 March 2001	Renewal.
•	20 September 2000	Change to the Safety Warnings.
•	15 May 2000	Change to the manufacturer and assembler of dosage form.
•	24 June 1997	Change in the primary packaging specification.