

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS Telephone +44 (0)1932 336911

Post Authorisation Assessments

Spectam Injectable 10% w/v Solution for Injection Vm 15052/4012

	00.0-1-10000	Observed in the MALL eddinger from Oscie Aut. 111. 111
•	06 October 2022	Change in the MAH address, from Ceva Animal Health
		Ltd, Unit 3, Anglo Office Park, White Lion Road,
		Amersham, Buckinghamshire, HP7 9FB to Ceva Animal
		Health Ltd, Explorer House, Mercury Park, Wycombe
		Lane, Wooburn Green, High Wycombe,
		Buckinghamshire, HP10 0HH, United Kingdom.
•	12 November 2020	Submission of an updated Ph. Eur. certificate of
		suitability for an active substance from an already
		approved manufacturer.
•	08 January 2016	Submission of an updated certificate of suitability.
•	23 September 2011	Variation to change the address of the Marketing
		Authorisation Holder.
•	31 March 2011	Addition of an active substance manufacturer.
•	29 October 2008	Variation to bring the SPC/Labelling in line with the
		Veterinary Regulations, 2005. Transfer of the legal
		category from POM to POM-V.
•	09 November 2007	Renewal.
•	02 January 2003	Change of address of Marketing Authorisation Holder.
•	31 October 2001	Renewal.
•	05 January 2001	Variation to change the name and address of the
		Marketing Authorisation/ATC Holder.
•	14 August 1998	Change of licence number.
•	06 December 1995	Addition of a dosage form manufacturer.
•	27 September 1995	Addition of a manufacturer of the dosage form.