



Post Authorisation Assessments

Spectam Injectable 10% w/v Solution for Injection Vm 14966/5068

04 November 2025	Change in legal entity of MAH from Ceva Animal Health Ltd, Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH, United Kingdom to Ceva Sante Animale, 8 rue de Logrono, 33500 Libourne, France.
17 June 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
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.