

Post Authorisation Assessments

Ketofen 1% Solution for Injection Vm 14966/5084

11 November 2025	Change of legal entity of the Marketing Authorisation Holder 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.
30 July 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
11 October 2022	Change in the address of the MAH from Unit 3 Anglo Office Park, White Lion Road Amersham, Buckinghamshire HP7 9FB to Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH, United Kingdom.
23 August 2017	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
13 June 2017	Change of MAH address from Merial Animal Health Limited to Ceva Animal Health Ltd. Change in distributor details from Merial Animal Health Limited to Ceva Animal Health Ltd.
01 March 2017	Addition of a manufacturer responsible for batch release of the finished product. Addition of a secondary packaging site of the finished product.
01 March 2017	Addition of a new specification parameter to the specification with its corresponding test method of the finished product Changes to a test procedure for the finished product.
14 February 2017	Deletion of a manufacturing site for an active substance. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
16 February 2011	Variation to submit an updated Certificate of Suitability for an already approved Manufacturing Site.
16 February 2011	Variation concerning the addition of a Marketing Authorisation Holder.
14 March 2007	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
14 November 2006	Renewal.

22 August 2006	Variation to update section of Dossier.
11 August 2005	Variation to update section of Dossier.
11 August 2005	Variation to update section of Dossier.
11 August 2005	Variation to update section of Dossier.
15 May 2003	Renewal.
06 September 2002	Harmonisation of the SPC.
30 November 1998	Variation to change the name/address of the PL/ATC Holder.
27 August 1997	Renewal.
16 May 1995	Variation to change the Assembler of the Dosage Form.