



Post Authorisation Assessments

Ketofen 1% Solution for Injection Vm 15052/4145

•	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.