



Post Authorisation Assessments

Ketofen 20 mg Tablets Vm 15052/4147

•	14 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.
•	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	Submission of an updated Certificate of Suitability for an already approved site of Manufacture.
•	16 February 2011	Variation concerning the addition of a Marketing Authorisation Holder.
•	29 July 2009	Variation to make a minor change to the manufacturing process of the finished product.
•	17 March 2009	Variation to change the shelf life of the finished product (as packaged for sale).
•	31 January 2007	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	11 October 2006	Renewal.
•	20 July 2005	Variation to update a section of the Dossier.
•	20 July 2005	Variation to update a section of the Dossier.
•	20 July 2005	Variation to update a section of the Dossier.
•	07 February 2003	Renewal.
•	31 January 2002	Addition of a new therapeutic purpose.
•	30 November 1998	Change of Marketing Authorisation Holder.
•	24 September 1997	Renewal.
•	16 April 1995	Variation concerning the Assembler of Dosage Form.