



## Post Authorisation Assessments

### Ketofen 5 mg Tablets Vm 15052/4148

•	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	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.
•	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.
•	31 January 2007	Update SPC/Labelling and Legal Category in line with the Veterinary Regulations, 2005.
•	11 October 2006	Renewal.
•	20 July 2005	Variation to update section of Dossier.
•	20 July 2005	Variation to update section of Dossier.
•	20 July 2005	Variation to update section of Dossier.
•	11 February 2003	Renewal.
•	31 January 2002	Changes to Therapeutic Use section of SPC.
•	30 November 1998	Change in the name and address of the Licence Holder.
•	12 September 1997	Renewal.