

## Post Authorisation Assessments

### Ketofen 5 mg Tablets Vm 14966/3038

03 October 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.
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.