Veterinary Medicines Directorate

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Post Authorisation Assessments

Ketofen 10% Solution for Injection

Vm 15052/4146

•	30 July 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
•	20 February 2023	Addition of manufacturing site responsible for radiosterilisation of plastic vials.
•	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.
•	29 January 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	08 August 2019	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	07 August 2019	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product. Addition of a manufacturing site of the finished product. Addition of a site where batch control/testing takes place. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Deletion of a pack size of the finished product.
•	05 June 2019	Part II harmonisation.
•	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 March 2017	Replacement to a test procedure for the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product.
•	07 March 2017	Addition of a manufacturer responsible for batch release of the finished product. Addition of a secondary packaging site of 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.
•	25 June 2014	Addition of 'reducing pain associated with lameness' to the therapeutic indication for cattle.
•	16 February 2011	Submission of an updated Certificate of Suitability for an already approved Manufacturing site.
•	16 February 2011	Variation concerning the addition of a Marketing Authorisation Holder.
•	18 April 2007	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	21 August 2006	Renewal.
•	07 July 2004	Change in the pack details.
•	07 May 2004	Change in the Batch Size of the finished product.
•	02 April 2004	Change in the composition of the product packaging.
•	02 April 2004	Variation to comply with Pharmacopeia.
•	02 April 2004	Variation to comply with Pharmacopeia.
•	09 April 2003	Renewal.
•	26 April 2002	Variation to update section of Dossier.
•	18 June 1998	Change of Marketing Authorisation Holder.
•	29 May 1997	Addition of a target species.
•	18 April 1997	Renewal.
•	16 February 1996	Addition of a target species.
•	08 February 1995	Variation concerning the Assembler of Dosage Form.