Veterinary Medicines Directorate

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Post Authorisation Assessments

Buprecare Multidose 0.3 mg/ml Solution for Injection for Dogs and Cats

Vm 32742/4025

•	25 April 2023	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance.
•	11 August 2022	Change of MAH: from Animalcare Ltd, 10 Great North Way, York Business Park, Nether Poppleton, York, YO26 6RB, United Kingdom to Ecuphar NV, Legeweg 157-i, 8020 Oostkamp, Belgium.
•	14 October 2021	Replacement of a manufacturer responsible for batch release including batch control/testing. Deletion of a non-significant in-process test applied during the manufacture of the finished product. Replacement of a secondary packaging site of the finished product. Submission of a new Ph. Eur. certificate of suitability for an active substance (used in manufacturing process of active) from a new manufacturer. Minor change in the manufacturing process of an immediate release oral solutions. Replacement of a manufacturing site of the finished product.
•	23 October 2018	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change in the contact details of 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.
•	11 October 2018	Change in the invented name of the veterinary medicinal product from Buprenovet to Buprecare in DE and AT.
•	16 April 2018	Change of RMS from UK to IE.
•	28 November 2017	Repeat Use application to add 10 new member states
•	08 August 2017	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	17 November 2016	Renewal – UK as RMS.
•	26 February 2015	Change in distributor details.
•	08 August 2013	Change in the address of the Marketing Authorisation Holder and change to the QPPV contact details.