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Post Authorisation Assessment

Buprecare 0.3 mg/ml Solution for Injection for Dogs and Cats $$\operatorname{Vm} 32742/4024$$

	19 March 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (NI) Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
• 0	08 March 2024	Approval of mock-ups.
• 1	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.
• 2	26 October 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
	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.
• 1	11 October 2018	Change in the invented name of the veterinary medicinal product from Buprenovet to Buprecare in DE and AT.
• 1	16 April 2018	Change of RMS from UK to IE.
	08 August 2017	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
	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.
• C	03 June 2013	Renewal MA
• 1	14 December 2012	Change to batch release arrangements and quality control testing of the finished product.
• 1	14 December 2012	Change in shape or dimensions of the container or closure (immediate packaging).
• 1	14 December 2012	Change in batch size (including batch size ranges) of the finished product.
• 1	14 December 2012	Change in the manufacturing process of the finished product.
• 1	14 December 2012	Change in the manufacturing process of the finished product.
	14 December 2012	Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product.
• C	01 July 2008	Change in the name of the manufacturing site.