Veterinary Medicines Directorate

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Post Authorisation Assessments

Cephacare Flavour 50 mg Tablets for Cats and Dogs

Vm 32742/4029

•	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)
•	09 October 2023	Deletion of a non-significant specification parameter in the specification parameters of the finished product. (GB)
•	12 June 2023	Minor changes to an approved test procedure for the finished product. (NI)
•	10 March 2023	Minor changes to an approved test procedure for the finished product. (GB)
•	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.
•	31 May 2022	Changes to the labelling and/or package leaflet.
•	06 May 2022	Change in the specification limits of the finished product.
•	27 January 2021	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.
•	11 July 2018	Change in the number of units (tablets) in a pack outside the range of the currently approved pack sizes of the finished product.
•	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.
•	25 May 2017	Changes to a test procedure for the finished

		product. Changes to a test procedure for the finished product.
•	26 February 2015	Change in distributor details.
•	29 May 2014	To remove the breakability test from the release and shelf-life specification.
•	09 January 2014	Change to the MA holder address and changes to an existing pharmacovigilance system. Also deletion of a secondary packaging site and submission of a new Ph. Eur. Certificate of Suitability for a new manufacturer of the active substance.
•	12 December 2013	Renewal.
•	27 October 2009	To add a site for batch release.
•	24 September 2009	To add a secondary packaging site.
•	12 May 2009	Change in batch size of the finished product: up to 10-fold.