Veterinary Medicines Directorate

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Post Authorisation Assessments

Benazecare Flavour 20 mg Tablets for Dogs

Vm 32742/4037

•	10 July 2024	Change in the specification parameters or limits of the finished product. (NI)
•	03 July 2024	Deletion of a non-significant specification parameter in the specification parameters of the finished product. Deletion of a non-significant specification parameter in the specification parameters of the finished product. (NI)
•	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)
•	12 October 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 August 2022	Minor change in the manufacturing process.
•	30 September 2021	Change in the SPC, labelling or package leaflet following assessment of the same change for the reference 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.
•	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.
•	01 May 2014	Submission of a new Ph. Eur. Certificate of Suitability for a new manufacturer of the active substance.
•	11 July 2013	Submission of a new Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer. Change to comply with an update of a relevant monograph of Ph. Eur. Or national pharmacopoeia of a member state. Change in the name of the address of the MAH.

•	31 May 2012	Update Summary of Product Characteristics and product literature in line with an Article 34 referral.
•	10 February 2012	Deletion of a manufacturing site.
•	11 January 2012	Renewal – UK as RMS
•	23 September 2009	To re-formulate the product.
•	26 November 2008	To update Drug Master File