

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS Telephone +44 (0)1932 336911

Post Authorisation Assessments

Metrobactin 250 mg Tablets for Dogs and Cats $$\operatorname{Vm}\,50406/4016$$

•	13 December 2023	Submission of a new certificate of suitability. (NI)
•	07 September 2023	Submission of a new Ph. Eur. CEP from a manufacturer for
		a non-sterile active substance.
•	07 April 2022	Change of MAH from Le Vet Beheer B.V. Wilgenweg 7,
		3421 TV Oudewater, The Netherlands to Dechra Regulatory B.V. Handelsweg 25, 5531 AE Bladel, The Netherlands.
•	30 July 2021	Minor change in the manufacturing process of the finished
	30 July 2021	product.
		Addition of a manufacturer responsible for batch release including batch control/testing.
		Addition of a secondary packaging site of the finished
		product.
		Addition of a primary packaging site of the finished product.
		Addition of a manufacturing site of the finished product.
•	11 February 2021	Renewal – UK as CMS.
•	10 September 2020	Minor change in the manufacturing process of the finished product.
•	20 February 2020	Change in the SPC, labelling or package leaflet of
		veterinary medicinal products intended to implement the outcome of a procedure concerning PSUR.
•	15 August 2019	Introduction of a new pharmacovigilance system.
•	22 March 2019	Change of distributor to Dechra Veterinary Products Limited,
		Sansaw Business Park, Hadnall, Shrewsbury, Shropshire,
		SY4 4AS, United Kingdom.
•	10 July 2018	Changes to the labelling and package leaflet.
•	17 January 2017	Product name change in Poland only.
•	22 March 2016	Submission of a new certificate of suitability.