



Post Authorisation Assessments

Metrobactin 500 mg Tablets for Dogs and Cats Vm 50406/4017

•	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 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.