



Post Authorisation Assessments

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

11 December 2024	Update to ATC Vet Code due to an update by WHOCC. (GB and NI).
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.