



Post Authorisation Assessments

Spizobactin 3,000,000 IU / 500 mg Chewable Tablets for Dogs Vm 41821/4049

•	13 April 2024	Addition of a manufacturer responsible for batch release including batch control or testing of the finished product. Addition of a primary packaging site of the finished product. Addition of a secondary packaging site of the finished product. Addition of a new manufacturer of the active substance via submission of a Ph. Eur. CEP. (GB & NI)
•	13 April 2024	Removal of a lower limit of an in-process control applied during the manufacturing process. Change to correct discrepancy between an in-process control limit and the release specifications of the finished product. Addition of a manufacturing site of the finished product. (GB & NI)
•	13 April 2024	Update to a Ph. Eur. CEP for an already authorised manufacturer of an active substance. (GB)
•	03 November 2022	Renewal
•	06 March 2020	Introduction of a new pharmacovigilance system.
•	03 May 2018	Variation to obtain joint-labelling. Change in distributor details from Le Vet. Beheer B.V., Wilgenweg 7, 3421 TV Oudewater, The Netherlands to Dechra Veterinary Products Limited, Sansaw Business Park, Hadnall, Shrewsbury, Shropshire, SY4 4AS, United Kingdom.