



Post Authorisation Assessments

Fungiconazol 400 mg Tablets for Dogs Vm 50406/4028

•	11 May 2024	Submission of an updated Ph. Eur. CEP from an already approved manufacturer. (NI)
•	12 September 2023	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance, – starting material, reagent or intermediate used in the manufacturing process of the active substance, or – excipient. (GB)
•	16 May 2023	Change in 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.
•	24 March 2023	Addition of a manufacturer responsible for batch release including batch control. Addition of a manufacturer responsible for primary packaging. Addition of a manufacturer responsible for secondary packaging.
•	16 February 2023	Minor change to the manufacturing process of the finished product. Addition of a manufacturing site for the manufacture of the finished product.
•	05 November 2019	Introduction of a new pharmacovigilance system.
•	17 September 2019	Renewal: UK as CMS
•	26 April 2019	- Changes to the labelling, or the package leaflet, which are not connected with the SPC - Change of distributor from: Animalcare Ltd., 10 Great North Way, York, YO26 6RN United Kingdom, to: Dechra Veterinary Products Limited, Sansaw Business Park, Hadnall, Shrewsbury, Shropshire SY4 4AS, United Kingdom