



Post Authorisation Assessments

Vitofyllin 50 mg Film-coated Tablets for Dogs Vm 32829/5000

•	14 July 2023	Addition of a Local Representative Animalcare Ltd, Moorside, Monks Cross, York YO32 9GZ, United Kingdom, E-mail: animalcare@animalcare.co.uk, Tel: +44 (0)330 8189 717.
•	12 January 2023	Change of the MAH from Animalcare Ltd, 10 Great North Way, York Business Park, Nether Poppleton, York YO26 6RB, United Kingdom, to WDT-Wirtschaftsgenossenschaft deutscher Tierärzte eG, Siemensstr. 14, 30827 Garbsen, Lower Saxony, Germany.
•	08 December 2022	Alignment of the product information with the updated national QRD template.
•	18 November 2021	Change in the name of a manufacturer of the active substance. Deletion of a non-significant specification parameter of the finished product.
•	19 February 2020	Additional manufacturer of the active substance where no Ph. Eur. Certificate of Suitability is part of the approve - Same ASMF. Changes in the manufacturing process of the active substance.
•	18 June 2019	Introduction of a new pharmacovigilance system.
•	14 May 2018	Change of RMS from UK to DE.
•	08 August 2017	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	28 April 2017	Renewal – UK as RMS.
•	03 June 2015	Change in shelf life of finished product from 3yrs to 5yrs.
•	26 February 2015	Change in distributor details.
•	31 July 2014	Change to extend the re-test period for the active substance, from 2 years to 5 years.
•	08 August 2013	Change in the address of the Marketing Authorisation Holder. Change to the QPPV contact details.