



Post Authorisation Assessments

Vitofyllin 50 mg Film-coated Tablets for Dogs Vm 32829/3000

22 December 2024	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
19 November 2024	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>. (NI).
06 March 2023	Repeat use to add 16 new CMS.
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 version 9.0 of the 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.