



Post Authorisation Assessments

Vitofyllin 100 mg Film-coated Tablet for Dogs Vm 32829/3001

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| • | 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. |