



Post Authorisation Assessments

Vivitonin 50 mg Tablets

Vm 06376/4074

10 January 2025	Substantial changes in the updated version of the ASMF of Propentofylline.
19 December 2024	Approval of mock ups.
23 November 2024	Minor change to an approved test procedure for the finished product.
11 November 2024	Addition of a new specification parameter to the immediate packaging specification with its corresponding test method. Tightening of specification limits of the immediate packaging of the finished product. Deletion of non-significant specification parameters of the immediate packaging of the finished product. Minor changes to an approved test procedure for immediate packaging of the finished product.
28 June 2024	Change in legal entity of the MAH from MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, MK7 7AJ, United Kingdom to Intervet International BV, Wim de Korverstraat 35, 5831 AN, Boxmeer, Netherlands.
19 January 2024	Tightening of specification limits for the finished product.
29 September 2023	Deletion of non-significant specification of the active substance.
08 February 2022	Minor change to an approved test procedure for the active substance used in the manufacturing process of the active substance.
14 April 2021	Minor change to an approved test procedure used in the manufacturing process of the active substance. Change in the specification parameters and/or limits used in the manufacturing process of the active substance.
01 April 2021	Change in the name of the MAH from Intervet UK Limited to MSD Animal Health UK Limited.
19 April 2018	Change in the name of a manufacturer used in the manufacture of the active substance.
01 November 2016	Deletion of a manufacturer of the active substance.
23 December 2015	Change in test procedure for the finished product
14 November 2013	Variation to make amendments to section 4.6 and 4.10 of the SPC.
27 September 2013	Variation to change an active substance test procedure.
10 June 2013	Variation to reduce the finished product shelf life.
03 August 2010	Variation to change the process controls relating the the tablet specification.
21 July 2007	Deletion of an assembler of dosage form.
19 October 2006	Variation to Bring the SPC/ Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category.

21 June 2006	Variation to change the finished product shelf life.
24 March 2006	Renewal.
20 April 2005	Variation to change the distributor in Northern Ireland.
30 April 2003	Renewal.
24 July 2002	Change of active substance manufacturer.
23 July 2002	Change of route of synthesis of the active substance.
25 October 2001	Change of the product specification.
22 August 2001	Change of manufacturer of dosage form.
03 July 2001	Addition of a distributor in Northern Ireland.
17 March 2000	Change of the name and address of the Marketing Authorisation Holder.
25 January 2000	Variation concerning the Dosage Particulars.
30 March 1999	Deletion of an excipient from the finished product formulation.
18 August 1997	Renewal.
29 May 1997	Addition of a manufacturer of dosage form.
27 January 1997	Change of Marketing Authorisation Holder.