



Post Authorisation Assessments

Vivitonin 50 mg tablets

Vm 01708/4417

•	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.