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Post Authorisation Assessments

Vivitonin 100 mg Tablets Vm 01708/4446

•	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 change Section 4.6 of the SPC.
•	27 September 2013	Variation to change a test procedure for the active substance.
•	10 June 2013	Variation to update the shelf life.
•	03 August 2010	Variation to change the in-process controls relating to the tablet.
•	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 from POM to POM-V.
•	28 June 2006	Variation to change an excipient of the finished product (relating to film coating)
•	28 June 2006	Variation to change an excipient of the finished product (relating to film coating)
•	28 June 2006	Extension of the shelf life of the finished product.
•	18 January 2006	Renewal.
•	12 May 2005	Change of distributor for Ireland.
•	25 July 2002	Change of the route of synthesis of the active substance.
•	25 July 2002	Change of active substance manufacturer.
•	24 October 2001	Change of finished product specification.
•	08 October 2001	Change of manufacturer of dosage form.
•	03 July 2001	Addition of a distributor in Northern Ireland.

•	17 March 2000	Change of name and address of the Marketing
		Authorisation Holder.
•	17 March 2000	Renewal.
•	17 November 1999	Amendments to the SPC and Package Leaflet
		concerning the dosage particulars.