Veterinary Medicines Directorate

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Post Authorisation Assessments

Vivitonin 100 mg Tablets

Vm 06376/4078

•	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 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.