Veterinary Medicines Directorate

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Post Authorisation Assessments

Estrumate 250 µg/ml Solution for Injection

Vm 01708/4598

•	14 October 2021	Update of a test procedure to comply with the updated Ph. Eur. monograph.
•	03 September 2021	Increase in batch size (1000L and 1500L) of the finished product. Minor change in the manufacturing process of the finished product.
•	11 June 2021	Deletion of a non-significant specification parameter of the finished product.
•	28 April 2021	Change in name of the MAH from Intervet UK Ltd, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ to MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ.
•	28 June 2016	Change(s) in the SPC, Labelling or Package Leaflet intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006.
•	31 July 2015	Approval of mock-ups.
•	18 April 2015	Change in colour of primary packaging material. Deletion of a non-significant specification parameter of the finished product. Change in test procedure for the finished product. Minor change in the manufacturing process of the finished product. Change in storage conditions of the finished product. Change in specification limits of the finished product. Change in composition of the finished product.
•	19 August 2014	Change in the name of manufacturer of the active substance.
•	26 March 2013	Change of MAH and change of distributor.
•	04 January 2013	Changes to the composition of the finished composition Changes of composition of parts of the immediate packaging Change in test procedure performed on the finished product Change in manufacturing process of the finished product Change in specification of the finished product
•	16 November 2012	Change to in use shelf life from 56 days to 28 days
•	23 November 2010	Change of name of manufacturing site of the finished product

•	19 May 2010	Change of shelf life from 3 years to 24 months
•	08 April 2010	Change in composition of a component of the packaging
•	26 November 2009	Changes to test procedure performed on the finished product
•	06 May 2009	Change of legal category from POM to POM-V Changes to the SPC and Package Literature to bring in line with new legislation
•	29 June 2007	Renewal
•	07 February 2003	Renewal
•	24 May 2001	Change to manufacturer of the active substance
•	01 September 1998	Change of withdrawal period
•	18 December 1997	Review