Veterinary Medicines Directorate

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Post Authorisation Assessments

Butox Swish, Pour-on Suspension 7.5 mg/ml

Vm 01708/4495

•	10 March 2023	Change(s) in the SPC, labelling or package leaflet intended to implement the outcome of a procedure. Changes to the labelling or the package leaflet which are not connected with the summary of product characteristics. Changes to the SPC and / or product literature: - Corrections to layout and harmonisation.
•	07 March 2023	Deletion of a non-significant specification parameter for an excipient.
•	14 February 2023	Deletion of a non-significant specification parameter of an excipient.
•	14 February 2023	Deletion of a test procedure for an excipient.
•	10 February 2023	Deletion of a test procedure of an excipient.
•	07 February 2022	Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product.
•	18 March 2021	Minor change to an approved test procedure for an excipient.
•	20 August 2020	Addition of a specification parameter with its corresponding test method of the finished product.
•	03 July 2020	Change in the name of the marketing authorisation holder from Intervet UK Ltd to MSD Animal Health UK Limited.
•	13 March 2018	Change in the name of a manufacturer used in the manufacture of the active substance.
•	17 January 2017	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product.
•	06 September 2016	Change in the name of the supplier of a starting material used in the manufacture of the active substance. Addition of two manufacturers of an intermediate used in the manufacturing process of the active substance.
•	26 April 2016	Change in the specification limits of the finished product.
•	01 May 2015	Change in name of the manufacturer of the active substance.
•	31 March 2015	Change in the specification parameters of an excipient.
•	17 June 2013	Changes in test procedures and tightening of

		specification limits for the active substance.
•	13 March 2012	Change of shelf life of the product as packaged for sale from 4 years to 3 years.
•	24 May 2011	Changes to update the SPC and product literature.
•	14 December 2010	Change of manufacturing site and update to the product specification.
•	16 April 2009	Renewal.
•	25 June 2008	Change to update the legal category from PML to POM-VPS and changes to bring the SPC and Product Literature in line with new legislation.
•	06 December 2005	Addition of a manufacturer of the active substance.
•	12 May 2005	Change of distributor.
•	19 November 2004	Changes made to the finished product specification.
•	30 March 2004	Addition of a distributor.