Veterinary Medicines Directorate

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Post Authorisation Assessments

Sputolosin Oral Powder 5 mg/g
Vm 08327/4303

•	08 October 2024	Change in shape or dimensions of the container of a non-sterile finished product. Change in shape or dimensions of the closure system of a non-sterile finished product.
•	22 June 2024	Change in dimensions of container for the finished product.
•	11 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
•	09 November 2018	Change of MAH, from Boehringer Ingelheim Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS to Boehringer Ingelheim Animal Health UK Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS.
•	09 December 2015	Change in part of the primary packaging material not in contact with the finished product.
•	18 December 2014	Deletion of a non-significant in-process test applied during the manufacture of the finished product.
•	09 September 2013	Variation to delete manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient.
•	21 November 2012	Grouped variation to remove a test method, delete a currentl used method, replace an existing method, to amend the test method for microbial contamination, to introduce a shelf life limit, and to add a specification to the degradation testing parameters.
•	04 October 2011	Variation to reduce the shelf life of the finished product.
•	09 February 2011	Variation to adapt the current testing specification to comply with the European Pharmacopoeia.
•	01 September 2010	Harmonisation of the SPC and mock-ups with Ireland.
•	30 January 2010	Variation to remove two sites of manufacture/assembly.
•	22 December 2009	Variation to update the specification testing for the finished product.
•	07 October 2009	Variation to make a change to a test procedure for the finished product.
•	09 May 2007	Variation to update the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of legal category from POM to POM-V.
•	21 March 2006	Renewal.
•	25 June 2003	Change of name of manufacturer and assembler.

•	10 January 2003	Variation to incorporate package leaflet text into the label.
•	21 November 2002	Addition of a site of manufacture, packaging, and assembly.
•	06 September 2002	Addition of an active substance manufacturer.
•	16 May 2002	Harmonisation of the SPC with Ireland.
•	12 September 2001	Change to the withdrawal period for horses.
•	17 November 2000	Renewal.
•	06 January 2000	Variation to change the assembly site of the dosage form.
•	29 June 1999	Change to the product safety warnings.
•	26 October 1998	Change of name of the manufacturer/assembler.
•	21 May 1998	Variation concerning the secondary assembler.
•	21 May 1998	Variation concerning the secondary assembler.
•	10 October 1996	Change to the safety warnings.
•	10 October 1996	Change to the ingredient specification.
•	10 October 1996	Change to the finished product specification.
•	10 October 1996	Change to the ingredient specification.
•	10 October 1996	Renewal.