Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

# Post Authorisation Assessments

## Sputolosin Oral Powder 5 mg/g

Vm 08327/5065

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| 08 October 2024 | Change in shape or dimensions of the container of a non-sterile finished product.<br>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. |

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| 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. |