Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911 Fax +44 (0)1932 336618

Post Authorisation Assessments

Norodine Granules

•	30 July 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	14 November 2016	Submission of an updated certificate of suitability.
•	09 January 2014	Change to the specification parameters for the finished product.
•	17 July 2013	Variation to update Ph. Eur. Certificates of Suitability for already approved Active Substance Manufacturers.
•	09 February 2009	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	07 October 2008	Deletion of a Manufacturer.
•	17 July 2008	Renewal.
•	08 May 2008	Variation to updated a Certificate of Suitability.
•	03 January 2008	Addition of an Active Substance Manufacturer.
•	28 December 2007	Addition of an Active Substance Manufacturer.
•	20 February 2007	Transfer of legal category from POM to POM-V.
•	05 August 2005	Addition of a Manufacturer/Assembler.
•	11 November 2004	Horse Passport Variation.
•	29 April 2004	Renewal.
•	16 April 2004	Addition of a Manufacturer.
•	28 June 2001	Variation to update Dosage Particulars.
•	19 October 1999	Addition of an Active Substance Manufacturer.
•	15 December 1998	Renewal.
•	19 November 1998	Addition of an Assembler of Dosage Form.
•	05 August 1998	Addition of an Assembler of Dosage Form.
•	24 April 1998	Addition of an Active Substance Manufacturer.
•	10 October 1996	Change of Active Substance Manufacturer.
•	11 August 1995	Update to product Safety Warnings.
•	19 April 1995	Variation to update Dosage Particulars.