Veterinary Medicines Directorate

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

Post Authorisation Assessments

Rilexine 600 mg Tablets for Dogs

Vm 05653/4132

•	09 February 2023	Change in test procedure for an excipient.
•	17 May 2022	Deletion of a non-significant in-process test applied during the manufacture of the finished product. Change in the specification parameters and/or limits of the immediate packaging of the finished product. Change in the specification parameters and/or limits of the immediate packaging of the finished product.
•	31 July 2020	Changes to the labelling and/or package leaflet.
•	10 January 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	23 January 2018	Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State. Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State
•	08 September 2017	Update of the test procedure to comply with the updated general Ph. Eur monograph. Increase in the shelf-life of the finished product as packaged for sale, from 24 to 36 months.
•	06 October 2016	Harmonisation of SPC and mock-ups with IE.
•	26 November 2015	Change in the specification parameters of the finished product. Deletion of a non-significant specification parameter.
•	19 March 2013	Addition of an active substance manufacturing with a European Pharmacopoeia Certificate of Suitability.
•	26 October 2012	Grouped variation to change a test procedure, reduce the total impurities limit of a test procedure, and to change the number of samples required for a test procedure.
•	27 April 2011	Renewal.
•	08 January 2009	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from POM to POM-V.
•	21 August 2008	Addition of packaging type.
•	04 October 2006	Variation to make an alteration to the SPC following advice from the VMD.