



## Post Authorisation Assessments

### Rilexine 300 mg Tablets for Dogs

Vm 05653/4133

• 09 February 2023	Change in test procedure for an excipient.
• 07 October 2022	Change in the specification parameters and/or limits of the finished product.
• 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 a new active substance manufacturer with a European Pharmacopoeial Certificate of Suitability.
• 26 October 2012	Grouped variation to change a finished product test procedure, reduce the number of samples required for a finished product test, and to reduce impurities limits for the finished product.
• 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 new pack size for the finished product.

•	04 October 2006	Variation concerning alterations to the SPC following advice from the VMD.
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