Veterinary Medicines Directorate

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

Post Authorisation Assessments

Selgian 10 mg Film-Coated Tablets

Vm 14966/4001

•	21 June 2023	Changes to the quality part of the dossier: Deletion of - one of the authorised bulk or final containers or immediate packaging of the finished product that does not lead to the complete deletion of a strength or pharmaceutical form.
•	31 March 2023	Harmonisation of the quality dossier: - Harmonisation of the quality dossier for the same purely national products and/or the same products approved in MR/DC procedures which are owned by the same MAH not participating in a former union interest referral procedure or SPC harmonisation procedure.
•	26 October 2022	Change in distributor details from Unit 3 Anglo Office Park, White Lion Road, Amersham, Buckinghamshire HP7 9FB to Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH, United Kingdom.
•	31 August 2022	Addition of a batch control/quality testing site.
•	10 May 2021	Reduction of the shelf life of the finished product as packaged for sale from 5 years to 3 years. Change in the specification parameters and/or limits of the finished product.
•	09 December 2014	Submission of an updated Ph. Eur. Certificate of Suitability.
•	25 October 2011	Change of address of the distributor.
•	13 December 2007	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from POM to POM-V.
•	10 January 2007	Renewal.
•	10 June 2005	Shelf life extension.
•	15 May 2005	Change of address of the distributor.
•	30 March 2004	Renewal.
•	25 July 2003	Harmonisation of the documentation between different strengths of the product.
•	03 January 2001	Addition of a presentation.
•	30 August 2000	Change of address of the Marketing Authorisation Holder.
•	29 August 2000	Change of product name.