

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

Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021, please refer to the EMA website.

Loxicom 1.5 mg/ml Oral Suspension for Dogs Vm 02000/5003

•	07 November 2024	Change in the SPC and package leaflet of a generic medicinal product following assessment of the same change for the reference product.
•	14 March 2023	Editorial changes to part 2 of the dossier.
•	14 March 2023	Change in dimensions of the container of a non-sterile finished product. Editorial changes to part 2 of the dossier.
•	08 March 2023	New certificate of suitability from a new manufacturer.
•	28 October 2022	Change in distributor details from Norbrook Laboratories (GB) Ltd, 1 Saxon Way East, Oakley Hay Industrial Estate, Corby, Northamptonshire, NN18 9EX, United Kingdom to Norbrook Laboratories Limited, Carnbane Industrial Estate, Newry, Co Down, BT35 6QQ, Northern Ireland.
•	12 July 2022	Change in the specification parameters and/or limits of the finished product.
•	04 May 2022	Deletion of a non-significant specification parameter of an excipient.
•	13 July 2021	Increase in batch size (a 1000 L batch size) of the finished product.