



Post Authorisation Assessments

Tranquiline 35 mg/ml Oral Gel for Dogs

Vm 56190/5002

•	11 May 2024	Addition of an administration device which is not an integrated part of the primary packaging.
•	19 October 2023	Change in legal entity of MA holder from Floris Animal Health Limited, Bath House, 6-8 Bath Street, Bristol BS1 6HL to Floris Holding BV, Kempenlandstraat 33 / 35, 5262 GK Vught, The Netherlands.
•	05 October 2023	Submission of updated QP declaration to verify GMP compliance of the active substance manufacturer.
•	23 December 2022	Increase in batch size range of the finished product.
•	23 February 2022	Dealignment
•	24 March 2021	Change of MAH from Floris Veterinaire Produkten BV, Kempenlandstraat 33 / 35, 5262 GK Vught, Netherlands to Floris Animal Health Ltd., Bath House 6-8, Bath Street Bristol BS1 6HL, United Kingdom.
•	17 February 2021	Changes to SPC and Product Literature following a Repeat Use procedure.
•	17 February 2021	Addition of a new specification parameter with its corresponding test method of an active substance used in the manufacturing process of the active substance. Replacement of a site where batch control/testing takes place.