



Post Authorisation Assessments

Tranquiline 35 mg/ml Oral Gel for Dogs Vm 56190/3002

•	28 June 2024	Addition of an administration device which is not an integrated part of the primary packaging.
•	05 October 2023	Submission of updated QP declaration to verify GMP compliance of the active substance manufacturer.
•	03 July 2023	Change in batch size of the finished product.
•	21 December 2022	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
•	23 February 2022	Change in the name and address of the marketing authorisation holder in Northern Ireland from Floris Animal Health Ltd., Bath House 6-8, Bath Street, Bristol, BS1 6HL, United Kingdom to Floris Holding BV, Kempenlandstraat 33 / 35, 5262 GK Vught, The Netherlands.
•	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.