



Post Authorisation Assessments

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

| | | |
|---|------------------|--|
| • | 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. |