



Post Authorisation Assessments

Sileo 0.1 mg/ml Oromucosal Gel for Dogs Vm 06043/5002

•	16 February 2024	Updating of packaging with UK VM numbers.
•	06 October 2023	Change in distributor details from Zoetis UK Limited, 1st Floor, Birchwood Building, 6 St. Andrew Street, Leatherhead, Surrey, KT22 7LP to TVM UK Animal Health Ltd. Kirtlington Business Centre, Slade Farm, Kirtlington, Oxfordshire, OX5 3JA, United Kingdom.
•	27 July 2023	Addition of GB Local Representative: TVM UK ANIMAL HEALTH LTD., Kirtlington Business Centre, Slade Farm, Kirtlington, Oxfordshire, OX5 3JA, United Kingdom.
•	01 June 2023	Change of Local Representative from TVM UK ANIMAL HEALTH LTD. to Orion Corporation, Orionintie 1, FI-02200 Espoo.
•	27 January 2023	Change of Local Representative from Zoetis UK Limited to TVM UK Animal Health LTD. Editorial changes to packaging material. A change in the supplier of the outer carton.
•	30 August 2022	The variation is to change the grade of raw materials used in the manufacturing of the immediate packaging of Sileo. The MAH took the opportunity to introduce editorial changes in part 2C.
•	27 July 2022	Change in shape or dimension of immediate packaging.
•	14 February 2022	Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State.
•	31 March 2021	Minor change to an approved test procedure for the active substance
•	08 March 2021	Deletion of a non-significant parameter of an active substance