Veterinary Medicines Directorate

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Post Authorisation Assessments

Flyclanil 5% Pour-on Suspension for Sheep

Vm 52127/5144

26 May 2026	Minor changes to the generic following identical changes to the reference product.
14 November 2025	Change in name of distributor from Elanco Europe Ltd to Elanco UK AH Ltd. Change in legal entity of MA holder from Elanco Europe Ltd, Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom to Elanco GmbH, Heinz-Lohmann Strasse 4, Groden, 27472 Cuxhaven, Germany.
10 April 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance.
28 April 2023	Introduction of a manufacturer of the active substance supported by an ASMF.
08 March 2022	Change in type of container for the finished product. Changes in the qualitative and quantitative composition of the immediate packaging of the finished product. Change in shape or dimensions of the container or closure (immediate packaging). Change in shape or dimensions of the container or closure (immediate packaging).
03 March 2022	Minor change in the manufacturing process of an immediate release of oral solutions. Minor change in the manufacturing process of an immediate release of oral solutions. Minor change in the manufacturing process of an immediate release of oral solutions. Minor change in the manufacturing process of an immediate release of oral solutions.