Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Fleanil Duo 402 mg / 361.8 mg Spot-on Solution for Very Large Dogs

Vm 62602/5002

07 September 2026	Change in legal entity of MA holder from Norbrook Laboratories Limited, Station Works, Camlough Road, Newry, Co. Down, BT35 6JP, United Kingdom to Naqua EU OÜ, Harju maakond, Tallinn, Kesklinna linnaosa, Tornimäe tn 5,10145, Estonia.
03 February 2026	Addition of a quality testing site for a finished product. (NI)
28 November 2025	Addition of a quality testing site for a finished product. (GB)
23 January 2024	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
18 November 2022	Change in the manufacturer of an intermediate used in the manufacture of the active substance. Extension of the retest period of the active substance.
28 October 2022	Change in distributor details from Norbrook Laboratories (GB) Ltd, 1 Saxon Way East, Oakley Hay Industrial Estate, Corby, Northamptonshire, NN18 9EX, United Kingdom to Norbrook Laboratories Limited, Carnbane Industrial Estate, Newry, Co Down, BT35 6QQ, Northern Ireland.
27 May 2022	Renewal
16 July 2021	Reduction of the shelf life of the finished product as packaged for sale from 3 years to 2 years.
07 May 2021	Addition of a new specification parameter to the specification with its corresponding test method.
06 January 2021	Change of specification(s) of a former non Pharmacopoeial active substance to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State.
22 October 2020	Change in the legal distribution category from NFA-VPS to AVM-GSL.
13 February 2020	Change in the SPC, labelling or package leaflet due to new data.
29 August 2019	Increase in the shelf-life of the finished product as packaged for sale, from 18 to 36 months.
30 July 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
09 July 2019	Addition of a manufacturer responsible for batch release of the finished product.