Veterinary Medicines Directorate

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Post Authorisation Assessments

Fiproclear Combo 402 mg / 361.8 mg Spot-on Solution for Very Large Dogs

Vm 02000/4411

•	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.
•	13 April 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.
•	28 August 2019	Increase in the shelf-life of the finished product as packaged for sale, from 24 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.
•	19 January 2018	Increase in the shelf-life of the finished product as packaged for sale, from 18 months to 2 years.