

Post Authorisation Assessments

Fiproclear Combo 50 mg / 60 mg Spot-on Solution for Cats and Ferrets Vm 02000/4407

	22 December 2023	Introduction of a summary of the PSMF or
•	22 December 2023	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.
•	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
	00. Assessed 0040	a Member State.
•	28 August 2019	Increase in the shelf-life of the finished product as
	30 July 2019	packaged for sale, from 24 to 36 months.
•		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.

VMD/L4/GAT/018/C