



Post Authorisation Assessments

FiprocLEAR 402 mg Spot-on Solution for Very Large Dogs Vm 02000/4353

•	16 January 2024	Change in dimensions of the container or closure (immediate packaging) of a non-sterile finished product. Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. (NI)
•	22 December 2023	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
•	31 July 2023	Change in dimensions of the container or closure (immediate packaging) of a non-sterile finished product. Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible.
•	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.
•	16 November 2021	Minor change in the manufacturing process of the finished product. Minor change in the manufacturing process of the finished product.
•	13 September 2021	Minor changes to an approved test procedure of the finished product.
•	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.
•	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.
•	31 July 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	10 May 2018	Renewal – UK as CMS.
•	19 June 2017	Addition of a secondary packaging site of the finished product.

•	02 February 2017	Update of the test procedure to comply with the updated general Ph. Eur monograph.
•	29 August 2014	Changes to the DDPS.
•	23 October 2013	Extension of shelf life of the product as packaged for sale from 2 years to 3 years.