



## Post Authorisation Assessments

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

|   |                   |   |
|---|-------------------|---|
| • | 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.<br>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.<br>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.  |