



## Post Authorisation Assessments

### Selapro 60 mg Spot-on Solution for Small Dogs (5.1–10.0 kg)

Vm 02000/4431

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| • | 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)   |
| • | 23 June 2023     | Unlimited renewal  |
| • | 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. |
| • | 12 November 2021 | Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.  |
| • | 01 November 2019 | Changes to the labelling and package leaflet.  |
| • | 22 August 2019   | Addition of a manufacturer responsible for batch release of the finished product.  |
| • | 01 August 2019   | Minor changes to an approved test procedure of the finished product.<br>Addition of a specification parameter with its corresponding test method of the finished product.  |
| • | 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.  |
| • | 14 June 2019     | Increase in the shelf-life of the finished product as packaged for sale, from 18 months to 24 months.  |
| • | 30 May 2019      | Replacement of a specification parameter with its corresponding test method of the finished product.   |
| • | 08 January 2019  | Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.   |