



Post Authorisation Assessments

Selapro 120 mg Spot-on Solution for Medium Dogs (10.1–20.0 kg) Vm 02000/4432

•	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)
•	22 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, BT35 6QQ, Co Down, 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. 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. 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.