

## Post Authorisation Assessments

### Solantel 50mg/ml Oral Suspension for Sheep

Vm 02000/4402

16 April 2025	Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. (NI) Minor changes: – to an approved test procedure for active substance, for the finished product, for the immediate packaging of the active substance or the finished product, or of a measuring or administration device. (NI)
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)
14 November 2023	Submission of an updated certificate of suitability.
24 May 2023	Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. Minor changes: – to an approved test procedure for active substance, for the finished product, for the immediate packaging of the active substance or the finished product, or of a measuring or administration device.
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.
21 June 2022	Update to AMSF.
06 May 2022	Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
20 August 2021	Renewal - UK as CMS.
14 October 2020	Change in shape or dimensions of the container or closure (immediate packaging)
04 September 2020	Change in storage conditions of the finished product.
16 September 2019	Addition of a manufacturer responsible for batch release 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.
09 November 2018	Change in RMS from UK to IE.
29 January 2018	Deletion of a non-significant specification parameter of the finished product.
01 August 2017	Update of the test procedure to comply with the updated general Ph. Eur monograph.

