Veterinary Medicines Directorate

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Post Authorisation Assessments

Solantel 50mg/ml Oral Suspension for Sheep

Vm 02000/4402

•	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.