Veterinary Medicines Directorate

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Post Authorisation Assessments

Spotinor 10 mg/ml Spot-on Solution for Cattle and Sheep

Vm 02000/4381

24 September 2026	Minor changes to the SPC and QRD text. (GB + NI).
November 2025	Addition of a site for quality testing for the finished product. (GB).
07 May 2025	Alignment of the product information with version 9.0* of the QRD template.
28 April 2024	Addition of a new specification parameter to the active substance specification. Editorial update of the ASMF of Deltamethrin. Minor changes to approved test procedures for the active substance. (NI)
28 April 2024	Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product. (NI)
28 April 2024	Addition of a site for batch testing for the finished product. (NI)
23 November 2023	Introduction of a summary of the PSMF. (NI)
14 April 2023	Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product. Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product. Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product. Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product. Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product. Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product. (GB)
14 March 2023	Editorial changes to part 2 of the dossier.
13 January 2023	Addition of a new specification parameter to the active substance specification. Editorial update of the ASMF of Deltamethrin. Minor changes to approved test procedures for the active substance.
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.
01 September 2020	Changes to the labelling and/or package leaflet.
29 July 2020	Change in storage conditions of the finished product.
22 May 2020	Change in immediate packaging of the active substance.
16 September 2019	Addition of a manufacturer responsible for batch release of the finished product.
21 August 2019	Renewal - UK as CMS.
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.
02 November 2018	Change in RMS from UK to IE.
13 September 2018	Minor changes to an approved test procedure of the finished product. Update of the test procedure to comply with the updated general Ph. Eur monograph.
28 February 2018	Change in the number of units (e.g. ampoules) in a pack within the range of the currently approved pack sizes of the finished product.
13 June 2017	Addition of a secondary packaging site of the finished product.
22 October 2015	Increase to the shelf-life of the finished product, from 2 years to 3 years.