Veterinary Medicines Directorate

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Post Authorisation Assessments

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

Vm 02000/4381

•	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)
•	April 2024	Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product. (NI)
•	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.