Veterinary Medicines Directorate

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Post Authorisation Assessments

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

Vm 02000/4382

•	05 November 2024	Change in the invented name of the veterinary medicinal product from Flydown 10 mg/ml Spot-on Solution for Cattle and Sheep to Norbrook Deltamethrin 10 mg/ml Spot-on Solution for Cattle and Sheep.
•	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 April 2023	Change in shape or dimensions of the container or closure of a non-sterile finished product. Change in shape or dimensions of the container or closure of a non-sterile finished product. Change in shape or dimensions of the container or closure of a non-sterile finished product. Change in shape or dimensions of the container or closure of a non-sterile finished product. Change in shape or dimensions of the container or closure of a non-sterile finished product. Change in shape or dimensions of the container or closure of a non-sterile finished product.
•	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.
•	03 January 2023	Change of Distributor address 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.
•	05 November 2020	Change in distributor details from Downland Marketing Limited, 15 Victoria Place, Carlisle, CA1 1EW to Downland Marketing Ltd, Main Mill, Warwick Mill Business Centre, Warwick Bridge, Carlisle, CA4 8RR.
•	01 September 2020	Change in storage conditions of the finished product.
•	19 August 2020	Changes to the labelling and package leaflet.
•	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.
•	23 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.
•	13 June 2017	Addition of a secondary packaging site of the finished product.
•	27 October 2015	Increase in the shelf-life of the finished product as packaged for sale, from 2 years to 3 years.