



Post Authorisation Assessments

Fly Off 12.5 mg/ml Pour-on Solution for Sheep Vm 50146/4019

•	03 February 2023	Change in the specification parameters of the immediate packaging of the finished product.
•	25 November 2022	Replacement of a quality control testing site for the finished product.
•	28 July 2022	Updated packaging specifications of the 1L backpack container. Updated packaging specifications of the 2.5L backpack container. Updated packaging specifications of the 5L backpack container.
•	26 January 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	19 November 2019	Renewal – UK as CMS.
•	24 July 2019	Change in the name and address of a manufacturer used in the manufacture of the active substance. Change in the name of a manufacturer of the finished product, also responsible for batch release. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	19 October 2018	Change of MAH, from Cross Vetpharm Group Ltd., Broomhill Road, Tallaght, Dublin 24, Ireland to Bimeda Animal Health Limited, 2 / 3 / 4 Airton Close, Tallaght, Dublin 24, Ireland.
•	23 March 2018	Change in RMS from UK to NL.
•	19 January 2018	Change in the invented name of the veterinary medicinal product from Starthrin 12.5 mg/ml Pour-On Solution for Sheep to Fly Off 12.5 mg/ml Pour-on Solution for Sheep.
•	22 December 2017	Minor changes to an approved test procedure of the finished product. Deletion of a non-significant specification parameter of the finished product.
•	24 November 2017	Change in shape or dimensions of the container or closure (immediate packaging) Change in the specification parameters and/or limits of an excipient Change in the specification parameters and/or limits of the immediate packaging of the finished product Change in test procedure for the finished product Change in test procedure for the finished product Change in the specification parameters and/or limits of an excipient

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•	13 November 2017	Introduction of a new pharmacovigilance system.
•	11 October 2017	Change in distributor details from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE, UK to United Farmers Ltd, The Coach House, 22 St John's Road, Corstorphine, Edinburgh, EH12 6NZ.
•	08 August 2017	Change of MAH, from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE, UK to Cross Vetpharm Group Limited, Broomhill Road, Tallaght, D24 E032, Ireland.
•	05 May 2015	Change in the QPPV contact details.