



Post Authorisation Assessments

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

Vm 50146/4019

•	23 November 2023	Quality testing site replacement for the finished product.
•	22 November 2023	Change to the in-process controls applied during the manufacture of the finished product. (NI)
•	21 November 2023	Change to the in-process controls applied during the manufacture of the finished product. (GB)
•	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

		<p>the immediate packaging of the finished product</p> <p>Change in test procedure for the finished product</p> <p>Change in test procedure for the finished product</p> <p>Change in the specification parameters and/or limits of an excipient</p> <p>Change in the specification parameters and/or limits of an excipient</p>
•	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.