



Post Authorisation Assessments

Topimec 0.8 mg/ml Oral Solution for Sheep Vm 08749/4029

17 December 2024	To update the calculation of ivermectin assay. (NI).
19 November 2024	To update the calculation of ivermectin assay. (GB).
30 March 2023	Change in the distributor address from Downland Marketing Ltd, 15 Victoria Place, Carlisle, CA1 1EW to Downland Marketing Ltd, Warwick Mill Business Centre, Warwick Bridge, Carlisle, CA4 8RR.
04 April 2022	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
21 June 2018	Change in the invented name of the veterinary medicinal product from: Topimec 0.8 mg/ml Oral Solution for Sheep to: Premadex 0.8 mg/ml Oral Solution for Sheep.
13 March 2018	Change in distributor details. From Chanelle Animal Health Ltd., 7 Rodney Street, Liverpool, L1 9HZ, UNITED KINGDOM to Downland Marketing Ltd., 15 Victoria Place, Carlisle, Cumbria, CA1 1EW, UNITED KINGDOM.
13 May 2015	Submission of a new certificate of suitability.
20 November 2014	Renewal.
13 October 2014	Change to the product's name in the UK only, from 'Animec 0.8 mg/ml Oral Solution for Sheep' to 'Topimec 0.8 mg/ml Oral Solution for Sheep'.
21 February 2012	Changes to the labelling or the package leaflet which are not connected with the Summary of Product Characteristics.
27 May 2011	Change in the batch size of the finished product.
27 May 2011	Submission of a new or updated Ph. Eur. certificate of suitability.
21 July 2010	To achieve joint labelling with the IMB.