Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Topimec Plus 10/100 mg/ml Solution for Injection for Cattle

Vm 11990/3000

•	01 February 2023	Other changes to the active substance: - Substantial changes in the updated version of the ASMF or the active substance part of the dossier.
•	16 December 2022	Updates of the QRD/SPC information in line with version 9.0* of the QRD template.
•	08 July 2022	Addition of a new Ph.Eur. certificate of suitability for a new manufacturer of an active substance.
•	29 April 2022	Increase in batch size (Up to 10-fold increase) of the active substance used in the manufacturing process of the active substance. Change in the manufacturer of a starting material / reagent/ intermediate used in the manufacturing process of the active substance.
•	30 September 2020	Change in the invented name of the veterinary medicinal product in BE, DE, and IT.
•	14 March 2019	Change of RMS from UK to PT.
•	24 July 2018	Addition of a secondary packaging site of the finished product.
•	19 July 2018	Deletion of manufacturing site for an active substance. Addition of a manufacturer of the active substance or addition of a site of manufacture.
•	20 September 2017	Change in the invented name of the veterinary medicinal product in the UK and PT from 'Alverin Plus 10/100 mg/ml Solution for Injection for Cattle' to 'Topimec Plus 10/100 mg/ml Solution for Injection for Cattle'. Change in the invented name of the veterinary medicinal product in FR from 'Levatum D 10/100 mg/ml Solution for Injection for Cattle' to 'Animec D 10/100 mg/ml Solution for Injection for Cattle'.
•	25 April 2017	Addition of a manufacturer of the active substance
•	26 October 2016	Renewal – UK as RMS
•	05 September 2016	Change in the (invented) name of the medicinal product in Spain only.
•	08 February 2016	Addition of a manufacturing site Change in the batch size
•	13 May 2015	Submission of an updated certificate of suitability.
•	24 March 2014	Change of distributor.