Veterinary Medicines Directorate

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

Post Authorisation Assessments

Modulis 100 mg/ml Oral Solution for Dogs

Vm 15052/4106

•	04 August 2023	Change in the shelf-life of the finished product.
•	18 January 2023	Deletion of a certificate of suitability for an active substance. Updated certificate of suitability from an already approved manufacture.
•	14 October 2022	Change in the address of the MAH from Unit 3 Anglo Office Park, White Lion Road Amersham, Buckinghamshire HP7 9FB to Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH, United Kingdom.
•	19 August 2022	Change in the appearance of the finish product. Change in the clarity of the finish product. Change outside the approved specifications limits range.
•	28 July 2020	Change in the specification limits of the finished product.
•	17 December 2019	Renewal – UK as CMS
•	18 October 2018	Replacement of a manufacturer responsible batch release of the finished product.
•	09 March 2018	Change in RMS from UK to FR.
•	28 February 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Extension of a re-test period of the active substance.
•	19 September 2017	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.
•	19 September 2017	Change in the name and/or address of the MAH in Spain only.
•	16 December 2016	Change in name of the site of batch release of the finished product.
•	06 September 2016	Change in the name an address of the MAH in Italy only.
•	29 June 2016	Introduction of a new pharmacovigilance system which has been assessed by the relevant national competent authority/EMA for another product of the same MAH.
•	16 June 2016	Change of MAH, from Sogeval to Ceva Animal Health Ltd.