Veterinary Medicines Directorate

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

Post Authorisation Assessments

EMEDOG 1 mg/ml Solution for Injection for Dogs

Vm 54982/3002

•	26 May 2023	One-off alignment of the product information with version 9.0* of the QRD templates.
•	04 May 2023	Repeat use procedure to add 8 member states
•	12 January 2023	Updated certificate of suitability from an already approved manufacturer.
•	10 October 2022	Updated certificate of suitability from an already approved manufacturer.
•	22 March 2022	Increase in the shelf-life of the finished product as packaged for sale, from 3 years to 4 years.
•	04 March 2022	Change of MAH from Domes Pharma SC, 57 Rue des Bardines, 63370 Lempdes, France to Domes Pharma, 3 Rue Andre Citroen, 63430 Pont-du-Chateau, France.
•	17 February 2022	Change in the manufacturing process of the finished product.
•	03 February 2022	Introduction of a new pharmacovigilance system.
•	21 December 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	20 May 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	17 March 2021	Change in the name of the marketing authorisation holder from Laboratoire TVM to Domes Pharma SC.
•	27 November 2020	Introduction of a new pharmacovigilance system.
•	25 November 2020	Changes to the date of the audit to verify GMP compliance of the manufacturer of the active substance.
•	11 June 2020	Renewal – UK as CMS
•	18 November 2019	Changes to the labelling and package leaflet.
•	10 October 2019	Change in distributor details from TVM UK Animal Health Ltd, Crown House, 2-8 Gloucester Road, Redhill, RH1 1FH, United Kingdom to TVM UK Animal Health Ltd, Building B, Kirtlington Business Centre, Kirtlington, Oxfordshire OX5 3JA, United Kingdom.
•	17 July 2019	Change in the number of units (e.g. ampoules, etc.) in a pack outside the range of the currently approved pack sizes of the finished product.
•	18 June 2019	Changes the SPC following PSUR assessment.
•	05 September 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of

		suitability for an active substance from an already approved manufacturer.
•	10 January 2018	Change in distributor name from FORUM ANIMAL HEALTH LIMITED to TVM UK ANIMAL HEALTH LTD.
•	21 December 2016	Change in distributor details. From Laboratoire TVM to Forum Animal Health. Changes to the labelling and package leaflet