Veterinary Medicines Directorate
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Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021, please refer to the EMA website.

Prevomax 10 mg/ml Solution for Injection for Dogs and Cats

Vm 50406/5002

•	17 November 2023	Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data. One-off alignment of the product information with version 9.0* of the QRD templates.
•	11 July 2023	Substantial changes in the updated version of the ASMF.
•	1 June 2023	Change in the name of an active substance master file (ASMF) holder.
•	27 April 2023	Unlimited renewal.
•	06 January 2023	Change of excipient specification from non-EU Pharmacopoeia to comply with Ph.Eur.
•	11 January 2022	Increase in batch size (up to 10-fold of the original batch size) of the active substance used in the manufacturing process of the active substance.
•	07 October 2021	Deletion of local representative information from the package leaflet.
•	06 October 2021	Addition of a manufacturer of the active substance or addition of a site of manufacture. Addition of a new specification parameter used in the manufacturing process of the active substance. Addition of a new specification parameter used in the manufacturing process of the active substance. Addition of a new specification parameter used in the manufacturing process of the active substance. Addition of a new specification parameter used in the manufacturing process of the active substance. Changes to a test procedure for the active substance. Changes to a test procedure for the active substance. Changes to a test procedure for the active substance.
•	06 August 2021	Change of MAH, from Le Vet Beheer B.V., Wilgenweg 7, 3421 TV Oudewater, The Netherlands to Dechra Regulatory B.V., Handelsweg 25, 5531 AE Bladel, The Netherlands.
•	06 August 2021	Increase in the shelf-life of the finished product as packaged for sale, from 2 years to 3 years. Change in storage conditions of the finished product.
•	04 June 2021	Changes to a test procedure for the finished product. Addition of a manufacturing site of the finished product. Change to part of the (primary) packaging material not in contact with the finished product formulation. Addition of a manufacturer responsible for batch release including batch control/testing. Addition of a secondary packaging site of the finished product.
•	02 June 2021	Extension of a re-test period of the active substance. Introduction of a new site of manufacture

		Tightening of specification limits used in the manufacturing process of the active substance