Veterinary Medicines Directorate

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Post Authorisation Assessments

TermaFlea Combo 402 mg/361.80 mg Spot-on Solution for Extra Large Dogs

Vm 39787/4133

•	04 May 2024	Substantial changes in the updated version of the ASMF or the active substance part of the dossier.
•	08 December 2023	Change in the name of a manufacturer of the finished product.
•	01 November 2023	Change in the limits of an active substance. Change in the specification parameters and/or limits of the finished product: - Change outside the approved specifications limits range.
•	18 August 2023	Editorial changes to labelling if inclusion in an upcoming procedure is not possible.
•	03 March 2023	Change in distribution category from POM-V to AVM-GSL for 30 products.
•	12 January 2023	Change in the invented name of the nationally authorised product range from Fleatix Plus to TermaFlea Combo.
•	05 July 2022	Minor changes to manufacturing process for the finished product. Change to the holding time of the bulk product.
•	21 April 2022	Change in the invented name of the veterinary medicinal product from TermaFlea Combo 402 mg/361.8 mg Spot on Solution for Extra Large Dogs to Fleatix Plus 402 mg/361.80 mg Spot-on Solution for Extra Large Dogs.