

Post Authorisation Assessments

Flea & Tick Treatment 402 mg Spot-on Solution for Very Large Dogs

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•	25 May 2017	Deletion of manufacturing site for an active substance.
•	22 December 2016	Mock-ups Approved.
		Change in Distributor details, from Vale Pharmaceuticals
		Ltd to Galpharm International Ltd.
•	13 December 2016	Addition of a supplier of packaging components.
•	15 November 2016	Introduction of a new pharmacovigilance system.
•	15 November 2016	Change in the invented name of the Veterinary Medicinal
		Product from FleaCidal to Flea & Tick Treatment.
•	22 June 2016	Change in the name of the Marketing Authorisation
		Holder from Elan Pharma International Limited to Perrigo
		Pharma International D.A.C.
•	20 April 2016	A Change in legal entity from Vale Pharmaceuticals
		Limited to Elan Pharma International Limited.
•	09 February 2016	To remove the FAD claim and FAD claim related wording
		from the SPC and product literature.
		To change the legal status from NFA-VPS to AVM-GSL
•	21 September 2015	Addition of pack sizes and deletion of a pack size.