Veterinary Medicines Directorate

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

Post Authorisation Assessments

Fipronil Pyriproxyfen Virbac 268 mg/80 mg Spot-on Solution for Large Dogs

Vm 05653/5032

•	27 June 2024	To increase the limits of the density at shelf-life in the finished product specifications.
•	30 November 2023	Minor change in of secondary packaging presentation. Minor changes to a test procedure carried out on the finished product. Minor changes to a test procedure carried out on the finished product.
•	24 October 2022	Change to an approved stability protocol of an active substance.
•	24 October 2022	Change in the name or address or contact details of a manufacturer of active substance.
•	20 October 2022	Other changes to the active substance: - Substantial changes in the updated version of the ASMF or the active substance part of the dossier.
•	25 October 2021	Change in the SPC, labelling or package leaflet due to new data.
•	25 November 2020	Change in the name of the manufacturer of the finished product. Deletion of manufacturing site for an active substance.
•	07 July 2020	Renewal - UK as CMS.
•	26 March 2020	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	21 January 2019	Change in RMS from UK to FR.
•	10 January 2019	Change in the invented name of the veterinary medicinal product from Effipro Duo to Fipronil Pyriproxyfen Virbac in the UK only.
•	12 October 2018	Change of specifications of a former non Pharmacopoeial active substance to comply with the Ph. Eur. monograph 2869.
•	19 June 2017	Minor changes to an approved test procedure of the finished product.
•	14 June 2017	Change in the name and address of a manufacturer used in the manufacture of the active substance. Addition of a manufacturer of the active substance.
•	15 March 2017	Minor change in the manufacturing process of the finished product. Changes in the qualitative and quantitative composition of the immediate packaging of the finished product.
•	14 October 2016	Update of mock ups following name change.
•	03 March 2016	Variation to change the product name in Belgium,

		Bulgaria, Cyprus, Czech Republic, Germany, Estonia, Greece, Spain, Hungary, Ireland, Italy, Lithuania, Luxembourg, Latvia, Netherlands, Poland, Portugal, Romania and Slovakia from EFFIPRO COMBO to EFFIPRO DUO.
•	9th December 2015	Change in the product name