



Post Authorisation Assessments

Fiprotec Combo 134 mg/ 120.6 mg Spot-on Solution for Medium Dogs Vm 01656/4119

•	05 November 2024	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI).
•	20 July 2024	Change in the manufacturer of a starting material used in the manufacturing process of the active substance.
•	13 October 2022	Approval of mock ups.
•	26 January 2022	Minor change in the manufacturing process of the finished product.
•	18 March 2021	Renewal - UK as CMS.
•	18 May 2020	Change of specifications of a former non Pharmacopoeial active substance to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State. Deletion of manufacturing site for an active substance.
•	1 November 2019	Minor change in the manufacturing process of the finished product.
•	20 August 2019	Addition of a secondary packaging site of the finished product.
•	08 March 2019	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	17 July 2018	Changes to a test procedure for the finished product.
•	11 May 2018	Variation to change the distribution category from NFA-VPS to AVM-GSL.
•	11 May 2018	Change in distributor details. From Beaphar UK Ltd, Homefield Road, Haverhill, CB9 8QP to Beaphar UK Ltd, Rook Tree Farm, Witherfield Road, Great Wratting, Suffolk, CB9 7HD.
•	28 February 2018	Change in the RMS from UK to DE.
•	26 February 2018	Changes to the EU SPC in order to implement changes suggested during a national variation.
•	20 October 2017	Change in the invented name of the veterinary medicinal product from Fiprotec Combo 134 mg/ 120.6 mg Spot-on Solution for Medium Dogs to AMFLEE combo 134 mg/ 120.6 mg spot-on solution for medium dogs in DE
•	25 May 2017	MRP (UK as RMS)
•	04 April 2017	Change of MAH from HCS bvba to KRKA, d.d., Novo mesto.
•	02 August 2016	Addition of a manufacturer of the active substance.
•	13 July 2016	To change the invented name of the veterinary medicinal product from Fypermid to Fiprotec Combo Update outer packaging for end user to include warnings

		from the SPC/package leaflet
•	04 May 2016	Change in legal category from POM-V to NFA-VPS. Deletion of FAD claim from the SPC.
•	15 December 2015	Change in the invented name of the product from Fipronil + S-Methoprene HCS to Fypermid.