Veterinary Medicines Directorate

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Post Authorisation Assessments

Fiprotec Combo 402 mg/ 361.8 mg Spot-on Solution for Extra Large Dogs

Vm 01656/4121

13 July 2026	Change in the specification parameters of an excipient. (NI)
16 May 2026	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (NI)
22 April 2026	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance. (GB).
14 March 2026	Change in the specification parameters of an excipient. (GB)
22 October 2025	Removal of approved distributor: Henry Schein UK Holdings Limited, Medcare North, Gillingham, Kent, United Kingdom, ME8 0SB.
14 October 2025	Alignment of the product information with version 9.0* of the QRD templates.
14 July 2025	Change in the address of a site responsible for manufacturer of the finished product, batch control and primary & secondary packaging. Deletion of a quality control testing site for an active substance. (GB).
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.
26 January 2022	Minor change in the manufacturing process of the finished product.
12 February 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
11 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.