



Post Authorisation Assessments

Fiprotec Combo 268 mg/ 241.2 mg Spot-on Solution for Large Dogs

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| • | 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 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. |

