Veterinary Medicines Directorate

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Post Authorisation Assessments

Fipralone Duo 268 mg/80 mg Spot-on Solution for Large Dogs

Vm 17902/4086

12 December 2024	Change in the density specification of the finished product at shelf-life.
14 February 2024	Change in the name or address or contact details of a manufacturer of active substance. Change to an approved stability protocol of an active substance. (NI)
01 December 2023	Minor change in of secondary packaging presentation. (GB) Minor changes to a test procedure carried out on the finished product. (GB) Minor changes to a test procedure carried out on the finished product. (GB)
08 December 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 2022	Change in the name or address or contact details of a manufacturer of active substance.
24 October 2022	Change to an approved stability protocol of an active substance.
October 2022	Change to an approved stability protocol of an 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.
27 November 2020	Change in the name of the manufacturer of the finished product. Deletion of manufacturing site for an active substance.
19 June 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.
22 January 2019	Change in RMS from UK to FR.
12 October 2018	Change of specifications of a former non Pharmacopoeial active substance to comply with the Ph. Eur. monograph 2869.
09 January 2018	Change in the name of the manufacturer of the finished product.
26 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.
04 February 2016	Change in the invented name of the product in ES, IT, and NL only.

17 November 2015	To change the invented name of the medicinal product from 'Fipralone Combo' to 'Fipralone Duo' in UK and ‘Fiprokil Combo’ to ‘Fiprokil Duo’ in France.