Veterinary Medicines Directorate

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# Post Authorisation Assessments

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

Vm 17902/5014

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| 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.<br>Change to an approved stability protocol of an active substance. (NI) |
| 01 December 2023 | Minor change in of secondary packaging presentation. (GB)<br>Minor changes to a test procedure carried out on the finished product. (GB)<br>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.<br>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.<br>Addition of a manufacturer of the active substance. |
| 15 March 2017 | Minor change in the manufacturing process of the finished product.<br>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. |

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| 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. |