



Post Authorisation Assessments

Duoflect Spot-on Solution for Dogs 40-60 kg Vm 15052/4066

•	27 September 2022	Change in the MAH address, from Ceva Animal Health Ltd, Unit 3, Anglo Office Park, White Lion Road, Amersham, Buckinghamshire, HP7 9FB to Ceva Animal Health Ltd, Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH United Kingdom.
•	02 December 2021	Extension of a re-test period of the active substance. Minor change to the restricted part of an Active Substance Master File. Tightening of specification limits of an active substance used in the manufacturing process of the active substance. Updates to relevant active substance, packaging controls and specifications documentation.
•	15 July 2020	Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products.
•	03 July 2019	Repeat use application to add 9 member states
•	01 February 2019	Changes in the manufacturing process of the active substance.
•	29 January 2019	Renewal – UK CMS
•	25 July 2018	Deletion of manufacturing site for an active substance.
•	28 March 2018	Change in RMS from UK to FR.
•	27 September 2017	Changes to the labelling.
•	19 September 2017	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	19 September 2017	Change in the name and/or address of the MAH in Spain only.
•	05 July 2017	Changes to the labelling and package leaflet
•	02 September 2016	Changes to an existing pharmacovigilance system as described in the DDPS.
•	02 April 2015	Change to the invented product name from 'Fiprospot Duo' to 'Duoflect'.
•	11 September 2014	Variation to change the product name in Italy only, from 'Fiprospot Duo' to 'Strectis'.