Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Frontline Tri-Act Spot-on Solution for Dogs 20-40 kg

Vm 08327/4284

•	28 September 2023	Amendments to relevant sections of the SPC following the endorsement by the European Commission of the CVMP Opinion on the Article 83 referral regarding VMPs containing N-methyl pyrrolidone as an excipient. The outcome agreed at EU level should also be applied to all impacted GB and UK-wide licences.
•	13 April 2023	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
•	14 February 2023	Unlimited renewal.
•	22 October 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	11 February 2021	Change in the address of a manufacturer used in the manufacture of the active substance.
•	28 May 2020	Minor change in the manufacturing process of an immediate release solid oral dosage form.
•	28 May 2020	Change in the name of a manufacturer of the finished product, also responsible for batch release.
•	27 January 2020	Change in legal category from POM-V to NFA-VPS.
•	27 December 2019	Change in the SPC, labelling or package leaflet following assessment of the same change for the reference product. Re-wording of indication to specify killing effect against fleas and killing and repellent effects against ticks.
•	27 November 2019	Increase in the shelf-life of the finished product as packaged for sale, from 2 years to 3 years. Change to an approved stability protocol.
•	05 November 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	16 November 2018	Change in the name and address of the marketing authorisation holder from Merial Animal Health Limited, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex, CM19 5TG, United Kingdom to Boehringer Ingelheim Animal Health UK Limited, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS, United Kingdom.
•	16 November 2018	Change in the name and address of a supplier of the active substance used in the manufacture of the active substance. Change in the name of a manufacturer used in the manufacture of the active substance. Change of a re-test period / storage period of the active substance.

•	30 October 2018	Change of specification of a former non Pharmacopoeial active substance to comply with the Ph. Eur.
•	09 October 2018	Changes to a test procedure for the active substance.