Veterinary Medicines Directorate

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Post Authorisation Assessments

Frontline Combo 134.00 mg / 120.60 mg spot-on solution for dog M

Vm 08327/3012

05 February 2025	Minor changes to the labelling not connected with the SPC.
24 January 2025	Change in the batch size of the finished product.
24 January 2025	Minor change in the manufacturing process of the finished product.
15 October 2024	Change in the specification limits of the finished product. Change in the specification parameters and/or limits of the finished product.
15 October 2024	One-off alignment of the product information with version 9.0 of the QRD templates.
11 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
22 October 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
26 May 2021	Changes to a test procedure for the finished product.
22 July 2020	Addition of a site where batch control/testing takes place.
28 May 2020	Change in the name of a manufacturer of the finished product, also responsible for batch release.
05 November 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
08 October 2019	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product.
15 April 2019	Update to the ASMF
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.
13 November 2018	Change in the name of the manufacturer of the finished product.
29 August 2018	Change in the address of the supplier used for the manufacture of the active substance. Addition of a new specification parameter with its corresponding test method of an active substance used in the manufacturing process of the active substance. Change of specification(s) of a former non Pharmacopoeial active substance to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State.

23 May 2018	Change in the address of a manufacturing site used in the manufacture of the active substance. Deletion of manufacturing site for an active substance.
15 January 2018	Minor change in the manufacturing process of the finished product.
07 December 2017	Changes to the labelling and/or package leaflet.
02 November 2017	Minor changes to an approved test procedure of the finished product
24 October 2017	Minor changes to an approved test procedure of the finished product.
18 January 2016	Change to the retest period of the active substance.
14 January 2016	Change in the QPPV and/or QPPV contact details and/or back-up procedure
05 December 2014	To add a new presentation of 1 blister of 4 pipettes.
31 March 2014	To change the address of the MAH in Spain only.
27 March 2014	Deletion of a manufacturing site responsible for primary packaging.
23 January 2014	Change of MA holder address in Belgium only.
17 June 2013	Introduction of a parametric release of the manufacture of the finished product for one manufacturing site only
03 April 2013	Addition of a manufacturing site of secondary packaging Removal of a manufacturing site of primary and secondary packaging
15 August 2012	Update to section 4.3 of the SPC
16 May 2011	Updates to the SPC and Product Literature
25 October 2010	Addition of indications against *Dermacentor reticulatus*
30 September 2008	Approval of previously unseen mock ups
02 July 2008	Renewal
25 April 2008	Minor change in the manufacturing process of the active substance
03 April 2008	Change of manufacturing site for the active substance
14 September 2006	Change of legal category from POM to POM-V
18 June 2006	Minor changes in manufacturing process of the active substance
11 June 2004	Change of batch size