Veterinary Medicines Directorate

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Post Authorisation Assessments

Ectoline 134 mg Spot-on Solution for Medium Dogs

Vm 17902/5042

26 August 2025	Minor change to an approved test procedure for a finished product.
12 August 2025	Change to in-process tests or limits applied during the manufacture of the finished product.
24 June 2025	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI).
25 March 2020	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
05 February 2019	Renewal - UK as RMS.
12 October 2018	Change of specifications of a former non Pharmacopoeial active substance to comply with the Ph. Eur. monograph 2869.
08 October 2018	Change in RMS from UK to FR.
11 April 2018	Increase in the shelf-life of the finished product as packaged for sale, from 24 months to 36 months for the thermoformed pipettes.
30 January 2018	Deletion of a manufacturing site for 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.
09 December 2016	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
21 October 2015	To add an additional site of purification for the active substance.
22 January 2015	Change to the product name in Italy only.
19 January 2015	Addition of an active substance manufacturer. Changes to the specification limits.
23 September 2014	Change to an in-process test applied during the manufacture of the finished product.
03 July 2014	Change to the invented name of the finished product in Italy and Spain only.
02 July 2014	Renewal procedure.
19 November 2013	Repeat Use procedure.
27 September 2012	Deletion of a non-significant parameter used in the manufacturing process of the active substance. Increase in the batch size range of the active substance. Minor change to the purification process of the active substance.
31 August 2012	Change in primary packaging not in contact with the finished product.
31 January 2012	To change the invented name of the product in Italy.

25 August 2011	To add a pipette with a new shape.
25 August 2011	To add a new transparent pipette presentation.
10 March 2011	Addition of a new manufacturing site for secondary packaging.
10 March 2011	Change in the name of the Veterinary Medicinal Product to Ectoline 134 Spot On Solution for Medium Dogs.
23 February 2011	Change of Distributor.
23 July 2010	To increase the shelf life from 18 months to 24 months.
02 June 2010	Clarification regarding form of used pipettes.
26 November 2009	To change the trade name in France only to: Tick-Puss 134 mg spot-on solution for medium dogs.
12 August 2009	To change the name of the product from Alfamed 134 mg Spot on solution for medium dogs to 4Fleas Fipronil 134 mg Spot on solution for medium dogs.
22 July 2009	To change the distributor.