



Post Authorisation Assessments

Advantix 600 mg + 3000 mg Spot-on Solution for Dogs (> 40 kg ≤ 60 kg) Vm 52127/5127

12 September 2025	Change in name of distributor from Elanco Europe Ltd to Elanco UK AH Ltd. Change in legal entity of MA holder from Elanco Europe Ltd, Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom to Elanco GmbH, Heinz-Lohmann Strasse 4, Groden, 27472 Cuxhaven, Germany.
14 August 2025	Update to antiparasitic warnings as per EMA guideline. Alignment of the product information with version 9.0* of the QRD templates.
08 April 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance. (GB)
12 January 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
29 February 2024	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 (NMP) as an excipient.
21 February 2023	Change in the re-test period of the active substance.
13 February 2023	Change in the re-test period of the active substance.
27 September 2022	Unlimited renewal.
05 July 2022	Addition of a new specification parameter to the specification with its corresponding test method. Deletion of a non-significant specification parameter. Minor changes to an approved test procedure for an active substance. Tightening of specification limits for an active substance. Deletion of manufacturing site for an active substance. Change in the specification for an active substance. Changes in the manufacturing process of the active substance.
26 February 2021	Addition of a new therapeutic indication.
23 October 2020	Change of MAH, from Bayer plc, 400 South Oak Way, Green Park, Reading, Berkshire, RG2 6AD to Elanco Europe Ltd., Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom.
25 February 2020	Addition of a manufacturer of the active substance.
08 August 2019	Minor change to an approved test procedure for the active substance used in the manufacturing process of the active substance.

	<p>Minor change to an approved test procedure for the active substance used in the manufacturing process of the active substance.</p> <p>Tightening of specification limits of an intermediate used in the manufacturing process of the active substance.</p>
26 October 2018	<p>Change in the safety database of an existing pharmacovigilance system as described in the DDPS.</p>