Veterinary Medicines Directorate

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

Post Authorisation Assessments

Advantix 400 mg + 2000 mg Spot-on Solution for Dogs (> 25 kg ≤ 40 kg)

Vm 52127/3051

28 August 2026	Editorial amendments to clarify use of all four active substances against target parasites.
23 April 2026	Addition of contact details to report suspected adverse reactions for the marketing authorisation holder.
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)
22 January 2025	Deletion of one of the authorised final containers that does not lead to the complete deletion of a strength or pharmaceutical form.
22 December 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.
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.

08 August 2019	Minor change to an approved test procedure for the active substance used in the manufacturing process of the active substance. Minor change to an approved test procedure for the active substance used in the manufacturing process of the active substance. Tightening of specification limits of an intermediate used in the manufacturing
17 July 2019	Increase in batch size used in the manufacturing process of the active substance. Minor change to an approved test procedure for the active substance used in the manufacturing process of the active substance. Minor change to an approved test procedure for the active substance used in the manufacturing process of the active substance. Deletion of a test procedure for the active substance used in the manufacturing process of the active substance if an alternative test procedure is already authorised. Change in the name of a supplier of active substance. Minor change in the manufacturing process of the active substance. Change in manufacturer of the active substance. Change in limit of a starting material used in the manufacturing process of the active substance.
27 June 2019	Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Tightening of in-process limits applied during the manufacture of the finished product. Addition of a new container for the finished product. Change in the manufacturing process of the finished product.
26 October 2018	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
18 September 2018	Change in distributor details from Bayer plc, Animal Health Division, Strawberry Hill, Newbury, Berkshire, RG14 1JA to Bayer plc, 400 South Oak Way, Green park, Reading, Berkshire, RG2 6AD.
29 December 2017	Change in the address of the marketing authorisation holder from Animal Health Division Bayer House, Strawberry Hill, Newbury, Berkshire, RG14 1JA to 400 South Oak Way, Green Park, Reading, Berkshire, RG2 6AD.
24 October 2017	Change in the invented name of the veterinary medicinal product from Advantix Spot-on Solution for Dogs over 25 kg to Advantix Spot-on Solution for Dogs over 25 kg up to 40 kg. Addition of a new therapeutic indication.
31 March 2017	Change in the name of a manufacturer used in the manufacture of the active substance.
21 June 2016	Change(s) to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH
27 May 2016	Delete Unidrug Distribution Group Limited as a distributor.
14 August 2015	Change in pack size of the finished product.
01 October 2014	Change in name of the MAH in France only.
10 June 2013	Changes to labelling/package leaflet unconnected with the SPC.

20 July 2012	Change of in process test/limits applied during the manufacture of the finished product.
13 April 2012	Variation to make several changes to the manufacturing process and in-process controls of the active substance, and make changes to specification(s)/test procedures of starting materials and reagents/solvents used in the manufacture of the active substance.
22 December 2011	Change to in process tests/limits applied during manufacture of the active substance.
12 December 2011	Addition of a therapeutic indication.
23 February 2011	Change of distributor.
17 January 2011	Change in manufacturer of starting material/reagent/intermediate used in the manufacture of the active substance.
17 August 2009	Change in shelf life of finished product in final packaging from 3 to 5 years, and after opening from 18 months to 24 months.
25 June 2009	Renewal.
25 October 2007	Change in manufacturing process of the active substance.
24 August 2006	Corrections/simple text layout changes to SPC and Product literature.
07 July 2006	Change of name/address of manufacturer of the active substance.
16 March 2006	Addition of an Indication.
19 August 2004	Change in shelf life of finished product in final packaging from 2 to 3 years, and after opening from 1 year to 18 months.