Veterinary Medicines Directorate

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Post Authorisation Assessments

Advantage 250 Spot-on Solution for Dogs

Vm 00879/4098

01 April 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (GB).
18 January 2024	Deletion of a non-significant parameter from the shelf-life specification of the finished product. (NI)
12 January 2025	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.
19 November 2024	Deletion of a non-significant parameter from the shelf-life specification of the finished product. (GB).
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.
14 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.
03 October 2019	Update to SPC warnings.
14 November 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.
21 August 2018	Change in RMS from UK to AT.
09 January 2018	Changes to the labelling and package leaflet.
05 January 2018	Change in the address of the marketing authorisation holder from Bayer plc, Animal Health Division, Bayer House, Strawberry Hill, Newbury, Berkshire, RG14 1JA to Bayer plc, 400 South Oak Way, Green Park, Reading, Berkshire, RG2 6AD.
10 April 2017	Change in pack size of the finished product.
31 March 2017	Change in the name of a manufacturer used in the manufacture of the active substance.
27 May 2016	Delete a distributor.
18 May 2016	Changes to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH
28 January 2016	Replacement or addition of a manufacturing site for secondary packaging
16 July 2013	Changes to the packaging/product leaflet that are not connected to the SPC.
13 April 2012	Grouped variation: Change to the in process tests/limits applied

	during the manufacture of the active substance. Changes in the manufacturing process for the active substance. Changes to in-process tests/limits applied during the manufacture of the active substance. Changes in test procedure for active substance or starting material used in the manufacture of the active substance.
15 December 2011	Change to in process tests/limits applied during the manufacture of the active substance. Changes to specification parameters/limits of the active substance.
12 August 2011	Change in specification parameters/limits for an excipient.
09 February 2011	Change of distributor.
05 January 2011	Change in legal category from POM-V to NFA-VPS. Revision of indication terminology.
30 July 2010	Change to in process tests/limits applied during the manufacture of the finished product.
21 May 2010	Change of name/address of MAH.
02 April 2009	Update of excipient specification to comply with the European Pharmacopoeia.
04 September 2008	Change of MAH.
03 September 2008	Change of MAH address.
14 May 2008	To add the treatment of lice to the indications.
02 April 2008	Change of MAH name/address.
09 January 2008	Renewal.
20 June 2006	Change in name/address of manufacturer of active substance.
23 November 2005	Corrections/simple text layout changes to SPC or Product literature.
14 April 2005	Shelf life extension.
09 October 2003	Change of distributor.
14 March 2003	Renewal.
15 August 2002	Change to the pharmacological properties.
09 July 2002	Change in manufacturing process of the finished product.
19 February 2002	Repeat Use.
23 October 2000	Change in route of synthesis of active substance.
15 February 2000	Change in safety warnings.
27 January 2000	Addition of 2, 3 and 6 unit dose presentations.
07 January 2000	Update of licence particulars.
22 March 1999	Change in shelf life of unopened product from 2 years to 3 years.
19 February 1999	Change in safety warnings
08 August 1997	Decentralised procedure (UK as RMS)
19 March 1997	Addition of data dossier