Veterinary Medicines Directorate

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Post Authorisation Assessments

Advantage 40 Spot-on Solution for Dogs

Vm 00879/4102

01 April 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (GB).
18 January 2025	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.
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 Unidrug Distribution Group Limited as 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
27 January 2016	Replacement or addition of a manufacturing site for secondary packaging
16 July 2013	Variation to make changes to the labelling or package leaflets which are not connected to the SPC.
13 April 2012	Four changes in test procedure for active substance or starting material, reagent, or intermediate used in the manufacturing of

	the active substance. Four changes to in-process tests/limits applied during the manufacture of the active substance. Two changes in the manufacturing process of the active substance. Four changes in the specification parameters/limits of the active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance.
15 December 2011	One change to in process tests/limits applied during the manufacture of the active substance. Six changes in the specification parameters/limits of the active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance.
12 August 2011	Change in specification parameters and/or limits of an excipient.
02 March 2011	Change of distributor.
05 January 2011	Variation to change the Indications on the SPC and to change the legal category from POM-V and NFA-VPS.
30 July 2010	Change to in process tests/limits applied during the manufacturer of the finished product.
21 May 2010	Change in MAH name/address.
02 April 2009	Change to comply with Ph. Eur. Or a Member state national Pharmacopoeia.
04 September 2008	Variation to change the name and address of the MAH.
03 September 2008	Change of MAH name/address.
14 May 2008	Addition of an authorised Indiciation.
02 April 2008	Change of MAH name/address.
09 January 2008	Renewal.
20 June 2006	Change of name/address of a manufacturer of the active substance.
23 November 2005	Variation to update the packaging to improve legibility and clarity on the product labelling and package leaflet.
14 April 2005	Change in shelf life from 3 to 5 years.
09 October 2003	Change in distributor.
14 March 2003	Renewal.
15 August 2002	Addition of an indication.
09 July 2002	Change in the manufacturing process of the finished product.
19 February 2002	Repeat use procedure – UK as RMS.
23 October 2000	Change of the manufacturing process of the active substance.
15 February 200	Addition of a FAD claim.
27 January 2000	Addition of unit sizes.
07 January 2000	Harmonisation of the SPC.
22 March 1999	Change in shelf life from 2 to 3 years.
19 February 1999	Change in safety warnings.
08 August 1997	Mutual recognition procedure – UK as RMS.
19 March 1997	Update of licence particulars.