Veterinary Medicines Directorate

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Post Authorisation Assessments

Advantage 400 Spot-on Solution for Dogs

Vm 00879/4103

•	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.
•	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 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 update the branding of the products.
•	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	Change to in process tests/limits applied during the manufacture of the active substance.

		6 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.
•	09 February 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	Change of MAH.
•	03 September 2008	Change of MAH name/address.
•	14 May 2008	Addition of an 'Indication'.
•	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.
•	16 October 2003	Change of distributor.
•	14 March 2003	Renewal.
•	15 August 2002	Addition of an 'Indication'.
•	09 July 2002	Change in manufacturing process of the finished product.
•	19 February 2002	Repeat use procedure – UK as RMS.
•	23 October 2000	Change in manufacturing process of the active substance.
•	15 February 2000	Change to the safety warnings.
•	27 January 2000	Change to shelf-life.
•	27 January 2000	Addition of unit sizes.
•	25 February 1999	MRP (UK as RMS).