Veterinary Medicines Directorate

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Post Authorisation Assessments

Advantage 40 mg Spot-on Solution for Small Cats, Small Dogs and Pet Rabbits

Vm 00879/4100

•	14 November 2024	Deletion of a non-significant specification parameter in the shelf-life specification of the finished product.
•	19 December 2022	Extension of the re-test period of the active substance
•	07 December 2021	Amendment to information on use of the product in the Summary of Product Characteristics and on product literature, following a formal review of the safety data.
•	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.
•	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.
•	20 December 2017	Changes to the labelling.
•	05 May 2017	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
•	27 April 2017	Change in name of manufacturer of the active substance.
•	02 February 2017	Change in the number of units in a pack outside the range of the currently approved pack sizes of the finished product.
•	05 August 2016	Implementation of requested wording changes in section 4.6 (Adverse reactions (frequency and seriousness)) of the SPC.
•	27 May 2016	Delete a distributor.
•	07 July 2015	Replacement manufacturing site for secondary packaging.
•	21 February 2013	Changes to labelling and package leaflet that are not connected to the SPC.
•	13 April 2012	Changes in test procedure for active substance or starting material/reagent/intermediate used in the manufacture of the active substance. Change in specification parameters/limits of active substance, starting material/intermediate/reagent used in the manufacturing process of the active substance.

		Changes to the in process test/limits applied during the manufacture of the active substance.
•	07 December 2011	Tightening of the in process tests or limits applied during the manufacture of the active substance. Change to specification parameters and/or limits of active substance and reagent used in the manufacturing process of the active substance.
•	14 July 2011	Change in specification parameters and/or limits of excipients.
•	09 February 2011	Change of distributor.
•	12 January 2011	Change of legal category from POM-V to NFA-VPS. Addition of an indication and contraindication.
•	23 March 2010	Change of in-process tests/limits applied during manufacture of the finished product.
•	14 January 2009	Addition of an Indiciation.
•	06 January 2009	Variation to comply with Ph. Eur. or national Pharmacopoeia of a member state.
•	07 August 2008	Variation to bring the SPC and labels in line with new legislation and transfer of legal category from POM to POM-V.
•	02 June 2006	Change in name of manufacturer of active substance.
•	24 May 2006	Renewal.
•	11 January 2006	Corrections/simple text layout changes to the SPC/product literature.
•	29 April 2005	Extension of the product shelf life.
•	18 September 2003	Change of address of MAH.
•	23 October 2002	To include statement on the indications on the SPC and package leaflet.
•	19 June 2002	Change to production process for final product.