Veterinary Medicines Directorate

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Post Authorisation Assessments

Advantage 80 mg Spot-on Solution for Large Cats and Pet Rabbits

Vm 00879/4105

•	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.
•	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	Change Distributor details. Delete Unidrug Distribution Group Limited as a distributor.
•	21 February 2013	Change to the labelling and package leaflet which are not connected to the summary of product characteristics.
•	13 April 2012	Three changes in test procedure for active substance or starting material, reagent or intermediate used in the manufacture of the active substance. Four changes in the specification parameters/limits of an active substance, starting material, intermediate or reagent used in the manufacture 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.

•	07 December 2011	Change to in process tests/limits applied during manufacture of the active substance. Six changes in the specification parameters/limits of an active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance.
•	14 July 2011	Change in specification parameters/limits of an excipient.
•	09 February 2011	Change of distributor.
•	12 January 2011	Addition to indications and contraindications. Change of legal category from POM-V to NFA-VPS.
•	23 March 2010	Change to the in process tests/limits applied during manufacture of the finished product.
•	06 January 2009	Change to comply with Ph. Eur. Or a member state's national Pharmacopoeia.
•	01 April 2008	Renewal.
•	13 March 2008	Variation to bring the SPC and labels in line with the new legislation and to transfer the legal category from POM to POM-V.
•	02 June 2006	Change in name/address of a manufacturer of the active substance.
•	11 January 2006	Variation to update the packaging to improve legibility and clarity on the product labelling and leaflet.
•	29 April 2005	Extension of the product shelf life from 3 years to 5 years.