Veterinary Medicines Directorate

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Post Authorisation Assessments

Advantage 80 Spot-on Solution for Cats

•	16 September 2021	Amendments to the Summary of Product Characteristics and to the product literature with regard to safe use of the product, where a collar is worn by the target species.
•	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.
•	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 December 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.
•	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.
•	31 March 2017	Change in the name of a manufacturer used in the manufacture of the active substance.
•	02 February 2017	Change in pack size of the finished product.
•	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
•	17 September 2015	Change in product name in Austria only.
•	16 April 2014	Change in MAH
•	13 April 2012	Five changes to the test procedure for the active substance or starting material, reagent or intermediate used in the manufacturing process of the active substance. Two changes to the specification parameters/limits of an active substance, starting material, intermediate or reagent used in the manufacture of the active substance. Five changes to in process tests/limits applied during the

		manufacture of the active substance. Two changes in the manufacturing process of the active substance.
•	15 December 2011	Six changes in the specification parameters/limits of an active substance, starting material, intermediate or reagent used in the manufacture of the active substance. Change to in process test/limits applied during the manufacture of the active substance.
•	12 August 2011	Change to specification parameters/limits of an excipient.
•	02 March 2011	Change of distributor.
•	05 January 2011	Change in legal category from POM-V to NFA-VPS. Change to therapeutic indications regarding flea allergy dermatitis.
•	30 July 2010	Change to in process tests/limits applied during the manufacture of the finished product.
•	21 May 2010	Change in name/address of MAH.
•	02 April 2009	Update specification of an excipient to comply with Ph. Eur.
•	04 September 2008	Change of MAH.
•	03 September 2008	Change of MAH name/address.
•	02 April 2008	Change of MAH name/address.
•	09 January 2008	Renewal.
•	20 June 2006	Change in name of manufacturer of 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 of shelf life from 3 to 5 years.
•	18 February 2005	Corrections/text changes to the SPC and Labels.
•	09 October 2003	Change in 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).
•	22 May 2001	Addition of an FAD claim.
•	23 October 2000	Change of manufacturing process.
•	28 January 2000	Change of packaging.
•	22 March 1999	Change of shelf life from 2 to 3 years.
•	19 February 1999	Change of safety warnings.
•	08 August 1997	Mutual recognition procedure (UK as RMS).
•	19 March 1997	Update of licence particulars.