Veterinary Medicines Directorate

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Post Authorisation Assessments

Advantage 100 Spot-on Solution for Dogs

Vm 00879/4097

•	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.
•	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
•	28 January 2016	Replacement or addition of a manufacturing site for secondary packaging
•	16 July 2013	Changes to the labelling and or packaging leaflet which are not connected to the summary of product characteristics.
•	13 April 2012	Grouped variation to make several changes to the in-process tests and limits, specification parameters and limits of an active substance, test procedures, and manufacturing processes used during the manufacture of the active substance.
•	15 December 2011	Grouped variation to tighten the in-process tests and limits, and specification parameters used during the manufacturing process of the active substance.
•	12 August 2011	Variation to delete a specification parameter from an excipient.
•	09 February 2011	Variation to change the 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	Variation to change the in-process tests or limits applied during the manufacture of the finished product.
•	21 May 2010	Variation to change the MAH addresses for Belgium, Luxembourg and France.
•	02 April 2009	Variation to update the active substance specification to comply with the European Pharmacopoeia.
•	04 September 2008	Variation to change the MAH.
•	03 September 2008	Variation to change the name of the MAH in France.
•	14 May 2008	Addition to the authorised indications.
•	02 April 2008	Variation to change the MAH in Ireland.
•	09 January 2008	EU Renewal UK as RMS.
•	20 June 2006	Change the name of the manufacturer of the active substance.
•	23 November 2005	Variation to update the packaging.
•	14 April 2005	Extend the shelf-life of the product from 3 years to 5 years.
•	16 October 2003	Variation to change Distributor address.
•	14 March 2003	Renewal.
•	15 August 2002	Change to Pharmacological Properties.
•	09 July 2002	Variation to change the manufacturing process.
•	23 October 2000	Change of the route of synthesis of the active substance.
•	15 February 2000	Change to the safety warnings.
•	15 February 2000	Change to the safety warnings.
•	27 January 2000	Change to the size of the sterile containers.
•	07 January 2000	Harmonisation of SPC.
•	22 March 1999	Extension to shelf life.
•	19 February 1999	Additional User Safety Warning.
•	08 August 1997	MRP (UK=RMS).
•	19 March 1997	Update Licence Particulars.