



## Post Authorisation Assessments

### Advantage 40 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 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 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	Variation to make several changes to the manufacturing process and in-process controls of the active substance and make changes to specification(s)/test procedures of starting materials and reagents/solvents used in the manufacture of the active substance.
•	15 December 2011	Changes to the in-process tests and limits applied during the manufacture of the active substance. Changes in the specification parameters and limits of a reagent used in the manufacture of the active substance.
•	12 August 2011	Deletion of a specification parameter.
•	02 March 2011	Variation to change the distributor.
•	05 January 2011	Variation to change the Indications on the SPC. Transfer of the legal category from POM-V to NFA-VPS.
•	30 July 2010	Change to the in-process tests and limits applied during

		the manufacture of the finished product.
•	21 May 2010	Variation to change the address of the Marketing Authorisation Holder in Belgium, Luxembourg, and France.
•	02 April 2009	Variation to update the specification of an excipient.
•	04 September 2008	Variation to change the name and address of the Marketing Authorisation Holder.
•	03 September 2008	Variation to change the name of the Marketing Authorisation Holder in France.
•	02 April 2008	Variation to change the Marketing Authorisation Holder in Ireland.
•	09 January 2008	Renewal (UK as RMS).
•	20 June 2006	Variation to change the name of the active substance manufacturer.
•	23 November 2005	Variation to update the packaging.
•	14 April 2005	Extension of the finished product shelf life from 3 to 5 years.
•	18 February 2005	Addition of a packaging presentation.
•	09 October 2003	Change of distributor address.
•	14 March 2003	Renewal.
•	15 August 2002	Change to the pharmacological properties.
•	09 July 2002	Change in the manufacturing process.
•	19 February 2002	Repeat Use.
•	22 May 2001	Addition of an FAD claim.
•	23 October 2000	Change in the manufacturing process of the active substance.
•	28 January 2000	Addition of a unit size.
•	22 March 1999	Extension of shelf life.
•	19 February 1999	Addition of a user safety warning.
•	08 August 1997	MRP (UK as RMS).
•	19 March 1997	Variation to add data to the dossier.