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## **Post Authorisation Assessments**

## Advantage 40 Spot-on Solution for Cats Vm 00879/4101

| • | 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.  |
| • | 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,<br>Green Park, Reading, Berkshire, RG2 6AD to Elanco<br>Europe Ltd., Form 2, Bartley Way, Bartley Wood<br>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<br>the manufacture of the active substance. Changes in the<br>specification parameters and limits of a reagent used in<br>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.  |
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| 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.  |
|                   | 30 July 2010 21 May 2010  02 April 2009 04 September 2008  03 September 2008  02 April 2008  09 January 2008  20 June 2006  23 November 2005 14 April 2005  18 February 2005 09 October 2003 14 March 2003 15 August 2002 09 July 2002 19 February 2002 22 May 2001 23 October 2000  28 January 2000 28 January 2000 29 March 1999 19 February 1999 08 August 1997 |