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## **Post Authorisation Assessments**

## **Seresto 1.25 g + 0.56 g, Collar for Cats** Vm 00879/4160

| • | 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.  |
| • | 22 September 2021 | Addition of a manufacturer of the active substance.  |
| • | 26 March 2021     | Changes to the labelling and package leaflet.  |
| • | 02 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.   |
| • | 01 June 2020      | Replacement of an excipient with a comparable excipient.   |
| • | 02 March 2020     | Changes in the SPC, Labelling or Package Leaflet of veterinary medicinal products intended to implement the outcome of a procedure concerning PSUR.  |
| • | 14 January 2020   | Addition of a manufacturer of the active substance.  |
| • | 09 September 2019 | Change to part of the (primary) packaging material not in contact with the finished product formulation. Change in the number of units in a pack outside the range of the currently approved pack sizes of the finished product. Change in the number of units in a pack outside the range of the currently approved pack sizes of the finished product. |
| • | 26 October 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 December 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.   |
| • | 15 June 2017      | Change to in-process tests or limits applied during the manufacture of the finished product.   |
| • | 31 March 2017     | Change in the name of the manufacturer of the active substance.  |
| • | 16 December 2016  | Increase in the shelf-life of the finished product as packaged for sale, from 4 to 5 years.  |
| • | 08 June 2016      | Change(s) to a DDPS following the assessment of the same DDPS in relation to another medicinal product of  |

|                          | th         | ne same MAH.   |
|--------------------------|------------|--|
| • 08 June 20             | 16 R       | Renewal – UK as CMS.   |
| • 13 May 20 <sup>2</sup> | s<br>M     | Change in the name of the manufacture of the active ubstance.  Innor change to the test procedure of the active ubstance.  |
| 15 Februar               | y 2015 A   | ddition of specification parameters.   |
| 28 Novemb                | oer 2014 A | ssessment of revised product literature.   |
| • 14 May 20 <sup>2</sup> | S          | To include new therapeutic indications into the GPC/packaging information of Seresto in relation to the revention of the transmission of Feline Vector Borne Diseases in cats. |
| • 16 April 20            |            | Change to marketing authorisation holder in France only rom Bayer Santé to Bayer Healthcare.   |
| 07 Februar               | y 2014 S   | Significant change to the SPC regarding claim for use.   |
| 11 Decemb                |            | xtension of shelf of the product as packaged for sale om 30 months to 48 months.   |
| • 07 June 20             | 13 C       | Changes to section 4.6 Adverse Reactions of the SPC.   |