Veterinary Medicines Directorate

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Post Authorisation Assessments

Seresto 4.50 g + 2.03 g, Collar for Dogs > 8 kg

Vm 00879/4162

•	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.
•	23 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, Green Park, Reading, Berkshire, RG2 6AD to Elanco Europe Ltd., Form 2, Bartley Way, Bartley Wood 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.
•	19 July 2018	Modification of an approved indication. Modification of an approved indication.
•	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.

•	14 October 2016	Update to the package leaflet.
•	08 June 2016	Change(s) to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH.
•	08 June 2016	Renewal – UK as CMS.
•	22 September 2015	Change to section 4.6 of the SPC to implement the outcome of a PSUR assessment.
•	13 May 2015	Change in the name of the manufacture of the active substance. Minor change to the test procedure of the active substance.
•	15 February 2015	Addition of specification parameters.
•	28 November 2014	Approval of mock-ups.
•	25 November 2014	Removal of all references to Leishmania in Section 5.1 of the SPC in the UK and IE only.
•	14 May 2014	To include new therapeutic indications in the SPC/packaging information in relation to the prevention of the transmission of Canine Vector Borne Diseases and the treatment and prevention of the dog flea (*Ctenocephalides canis*) in dogs.
•	16 April 2014	Change to marketing authorisation holder in France only from Bayer Santé to Bayer Healthcare.
•	07 February 2014	Significant change to the SPC regarding claim for use.
•	11 December 2013	Extension of shelf of the product as packaged for sale from 30 months to 48 months.
•	07 June 2013	Changes to section 4.6 Adverse Reactions of the SPC.