Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Endectrid 100 mg + 25 mg Spot-on Solution for Medium Dogs

Vm 00879/4130

•	27 June 2024	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance.
•	13 February 2023	Harmonisation of the SPC and PL with those of the reference product.
•	12 January 2023	Changes to the labelling or the package leaflet section Adverse events.
•	19 December 2022	Extension of the re-test period of the active substance.
•	11 March 2022	Change to the name of the local representative. Change in the SPC, labelling or package leaflet following assessment of the same change for the reference product.
•	08 October 2021	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer. Minor change to an approved test procedure for the active substance used in the manufacturing process of the active substance. Introduction of a re-test period of the active substance.
•	09 September 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.
•	30 June 2020	Renewal - National.
•	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.
•	25 July 2018	Change in the SPC, labelling or package leaflet following assessment of the same change for the reference product.
•	27 July 2017	Change in the name of a manufacturer used in the manufacture of the active substance.
•	21 June 2017	Change in local representative from CVS (UK) Ltd. to MiGroup.
•	05 May 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
•	07 September 2016	Changes to SPC and labelling following assessment of the same change of the reference product.
•	22 July 2016	Addition of new pack size.
•	24 May 2016	Changes to a DDPS following the assessment of the

		same DDPS in relation to another medicinal product of the same MAH
•	19 May 2016	Change in the SPC, labelling or package leaflet following assessment of the same change for the reference product.
•	25 August 2015	Change in test procedure for the finished product.
•	30 July 2015	Addition of a manufacturing site for secondary packaging.
•	02 June 2015	Submission of an updated Certificate of Suitability.