



## Post Authorisation Assessments

### Endectrid 80 mg + 8 mg Spot-on Solution for Large Cats Vm 00879/4135

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| 14 April 2025     | Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).   |
| 27 November 2024  | Submission of a new Ph. Eur. CEP from a new manufacturer for a non-sterile active substance.  |
| 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.  |
| 19 December 2022  | Extension of the re-test period of the active substance   |
| 10 February 2022  | Change in the name of the local representative from MiGroup, Owen Road, Diss, Norfolk, IP22 4ER to MiPet, Owen Road, Diss, Norfolk, IP22 4ER.   |
| 12 November 2021  | 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.<br>Minor change to an approved test procedure for the active substance used in the manufacturing process of the active substance.<br>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.  |
| 01 July 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.  |

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| 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 |
| 25 August 2015    | Change in test procedure for the finished product.   |
| 30 July 2015      | Additional manufacturing site for secondary packaging.   |
| 30 June 2015      | Submission of an updated certificate of suitability.   |