



## Post Authorisation Assessments

### Prinocate 250 mg/62.5 mg Spot-on Solution for Large Dogs Vm 01656/4185

|   |                  |  |
|---|------------------|--|
| • | 15 May 2024      | Unlimited renewal  |
| • | May 2024         | Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)  |
| • | 14 May 2024      | Minor changes to an approved test procedure for the finished product. (NI)   |
| • | 03 April 2024    | Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance. (NI)  |
| • | 03 April 2024    | Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance. (GB)  |
| • | 03 April 2024    | Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State:– change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member.<br>Changes to the quality part of the dossier: Deletion of a manufacturing site for an active substance. (NI) |
| • | 30 November 2023 | Extension of the shelf life of the finished product.   |
| • | 29 March 2023    | Minor changes to an approved test procedure for the finished product.  |
| • | 08 March 2023    | Change to comply with an update of the relevant monograph of the Ph. Eur.<br>Deletion of a manufacturer of an active substance.  |
| • | 02 February 2021 | Minor change in the manufacturing process of the finished product.<br>Minor change in the manufacturing process of the finished product.   |
| • | 04 November 2020 | Minor changes to an approved test procedure of the finished product.   |
| • | 13 July 2020     | Introduction of a re-test period of the active substance.  |
| • | 28 May 2020      | Change to comply with Ph. Eur.   |
| • | 24 March 2020    | Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.   |