



Post Authorisation Assessments

Prinocate 100 mg/25 mg Spot-on Solution for Medium Dogs Vm 01656/4184

•	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. (NI) 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. Deletion of a manufacturer of an active substance.
•	02 February 2021	Minor change in the manufacturing process of the finished product. 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.