Veterinary Medicines Directorate

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Post Authorisation Assessments

Prinocate 250 mg/62.5 mg Spot-on Solution for Large Dogs

Vm 01656/4185

19 May 2026	Deletion of a manufacturing site for an active substance
16 May 2026	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (NI)
07 May 2026	Change in the specification limits of an excipient.
20 April 2026	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (GB)
19 December 2025	Minor change to an approved test procedure for an active substance. (NI)
17 November 2025	Deletion of a site of Batch control. Change in the address of a manufacture of the finished product. (GB + NI).
10 September 2025	Submission of a Ph. Eur. CEP for an active substance. (NI).
13 August 2025	Minor change to an approved test procedure for an active substance. (GB)
17 July 2025	Submission of a Ph. Eur. CEP for: — active substance. (GB).
13 June 2025	One-off alignment of the product information with version 9.0.
15 May 2024	Unlimited renewal (GB)
18 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. 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.

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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.