



Post Authorisation Assessments

Calmino Vet, 380/60/50 mg/ml Solution for Infusion for Cattle, Sheep and Pigs Vm 51467/4000

06 March 2025	Change in part of the primary packaging material not in contact with the finished product. Addition of a secondary packaging site. (GB & NI)
10 May 2024	Unlimited Renewal
04 May 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
02 April 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance.
15 December 2023	Change in test procedure for the finished product.
09 June 2023	Updated certificate of suitability from an already approved manufacturer. (NI)
09 June 2023	Change in any part of the primary packaging material not in contact with the finished product formulation - Addition of an alternative flip off cap and cover. (NI)
09 June 2023	Submission of a new certificate of suitability from a new manufacturer. (NI)
19 May 2023	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
18 January 2023	Updated certificate of suitability from an already approved manufacturer.
11 January 2023	Change in any part of the primary packaging material not in contact with the finished product formulation - Addition of an alternative flip off cap and cover.
11 January 2023	Addition of a new certificate of suitability from a new manufacturer.
04 January 2023	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance.
21 December 2022	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
17 February 2022	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
25 November 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.

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11 May 2021	Changes to the labelling and/or package leaflet.
14 January 2021	Change in the number of units (bottles) in a pack outside the range of the currently approved pack sizes of the finished product.