



Post Authorisation Assessments

Butasal 100 mg/ml + 0.05 mg/ml Solution for Injection for Horses, Cattle, Dogs and Cats Vm 51467/4002

•	01 December 2024	Change in the layout of the outer carton and bottle labels.
•	29 October 2024	Minor change in the manufacturing process of the finished product. Minor change in the manufacturing process of the finished product. Addition of a new 50 ml amber glass vial container. (GB & NI)
•	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)
•	30 April 2024	Change to comply with an update of the relevant monograph of the Ph. Eur. (NI) Deletion of a non-significant specification parameter of an active substance. (NI) Submission of an updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance. (NI)
•	18 April 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance. (GB)
•	28 February 2024	Change to comply with an update of the relevant monograph of the Ph. Eur. (GB) Deletion of a non-significant specification parameter of an active substance. (GB) Submission of an updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance. (GB)
•	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. (GB)
•	21 December 2022	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance. (NI)
•	21 December 2022	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (GB)
•	17 February 2022	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. (NI)
•	17 February 2022	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. (GB)