



Post Authorisation Assessments

Noroclav Intramammary Suspension for Lactating Cows

Vm 02000/5018

•	21 October 2024	Change in the intermediate manufacturing sites used in the manufacturing process of the active substance.
•	23 January 2024	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex (NI)
•	07 March 2023	Unlimited renewal.
•	22 November 2022	Submission of a new Ph.Eur certificate of suitability for an active substance.
•	28 October 2022	Change in distributor details from Norbrook Laboratories (GB) Ltd, 1 Saxon Way East, Oakley Hay Industrial Estate, Corby, Northamptonshire, NN18 9EX, United Kingdom to Norbrook Laboratories Limited, Carnbane Industrial Estate, Newry, Co Down, BT35 6QQ, Northern Ireland.
•	25 November 2021	Change in name of site of sterilisation.
•	13 August 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	06 November 2020	Minor changes to an approved test procedure of the finished product.
•	02 October 2020	Change in the invented name of the veterinary medicinal product from Combiclav Intramammary Suspension for Lactating Cows to Noroclav Intramammary Suspension for Lactating Cows in BE only.
•	03 February 2020	Change in control of the active substance.
•	20 January 2020	Change in control of excipient in the finished product.
•	25 September 2019	Repeat Use application to add 4 new member states
•	22 August 2019	Addition of the distributor to the QRD.
•	22 August 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	13 August 2019	Change in the invented name of the veterinary medicinal product from Anoffline Intramammary Suspension for Lactating Cows to Noroclav Intramammary Suspension for Lactating Cows.
•	30 July 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	11 June 2019	Increase in the shelf-life of the finished product as packaged for sale, from 18 months to 2 years.

•	10 October 2018	Change in RMS from UK to IE.
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