Veterinary Medicines Directorate

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Post Authorisation Assessments

Noroclav Intramammary Suspension for Lactating Cows

Vm 02000/5018

01 April 2025	One-off alignment of the product information with version 3 of the GB SPC/QRD template
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 Anofline 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.