Veterinary Medicines Directorate

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Post Authorisation Assessments

Combiclav Intramammary Suspension for Lactating Cows

Vm 02000/3009

27 July 2026	Addition of a secondary packaging site of a finished product.
17 October 2025	Change in the manufacturing process of the finished product.
02 July 2025	Minor changes to an approved test procedure.
02 April 2025	Alignment of the product information with version 9.0* of the QRD templates.
16 January 2024	Change in the intermediate manufacturing sites used in the manufacturing process of the active substance.
23 November 2023	Introduction of a summary of the PSMF. (NI)
03 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 Noroclav Intramammary Suspension for Lactating Cows to Combiclav Intramammary Suspension for Lactating Cows in BE only.
27 April 2020	Change in the invented name of the veterinary medicinal product from Ampredclav Intramammary Suspension for Lactating Cows to Combiclav Intramammary Suspension for Lactating Cows in the UK only.
10 January 2020	Change in control of excipients in the finished product.
10 January 2020	Change in control of the active substance.
19 November 2019	Addition of distributor Norbrook Laboratories (GB) Ltd, 1 Saxon Way East, Oakley Hay Industrial Estate, Corby, Northamptonshire, NN18 9EX,United Kingdom to QRD.
7 November 2019	Change in the SPC, labelling or package leaflet due to new data.
22 August 2019	Addition of a manufacturer responsible for batch release of the finished product.
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.

14 June 2019	Change in the invented name of the veterinary medicinal product to Noroclav Intramammary Suspension for Lactating Cows in BE, CZ, ES, HU, PT, SK
14 June 2019	Increase in the shelf-life of the finished product as packaged for sale, from 18 months to 24 months
10 October 2018	Change in RMS from UK to IE.