



Post Authorisation Assessments

Noroseal 2.6g Intramammary Suspension for Cattle

Vm 02000/5023

17 October 2025	Introduction of a manufacturer of the active substance supported by an ASMF.
12 March 2025	Addition of the indications onto the outer package and amendment to the classification section of the SPC and Package leaflet. (NI)
26 January 2025	Alignment of the product information with version 9.0* of the QRD templates.
05 December 2023	Changes in the SPC, labelling or package leaflet of a generic or hybrid medicinal product following assessment of the same changes for the reference product.
05 December 2023	Changes to the quality part of the dossier: Deletion of a non-significant in-process test during the manufacture of the finished product. (GB)
01 December 2023	Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product. (GB+NI)
23 November 2023	Introduction of a summary of the PSMF. (NI)
07 November 2023	Minor changes to an approved test procedure for the finished product. (GB)
07 November 2023	Minor changes to an approved test procedure for the finished product. (NI)
03 February 2023	Change in excipient specification to comply with Ph. Eur.
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.
18 October 2022	Change in excipient specification to comply with Ph. Eur (Aluminium Di-Tri Stearate).
25 November 2021	Change in name of site of sterilisation.
26 April 2021	Minor changes to an approved test procedure of the finished product.
28 August 2020	Changes to a test procedure for an excipient.
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.
26 July 2019	Addition of a manufacturer responsible for batch release of the finished product.
09 May 2019	Addition of a manufacturing site of the finished product.
11 February 2019	Qualitative and quantitative changes to the excipients.

04 February 2019	Change in RMS from UK to IE.
15 January 2019	Changes to the labelling and package leaflet.
24 October 2018	Change in the invented name of the veterinary medicinal product from NOROSEAL SUSPENSION INTRAMAMMAIRE POUR BOVINS to Dryseal Suspension Intramammaire pour Bovins in France only.
09 October 2018	Addition of a manufacturing site of the finished product.
02 October 2018	Change in manufacturing batch size
07 August 2018	Renewal UK as RMS
02 April 2015	Addition of a wipe to packaging. Removal of a statement from the SPC and package leaflet.
04 November 2014	Addition of warming advice to the SPC and package leaflet "Under cold conditions the product may be warmed to room temperature in a warm environment to aid syringeability. The product should be warmed in tepid water for 5 minutes".
25 September 2014	Change of QPPV and update to the DDPS.
15 August 2014	Addition of a site of manufacture. Change in immediate packaging of the finished product – addition of an orange plunger. Addition of a new 800kg batch size. Addition of an in-process test during the manufacture of the finished product.
05 June 2014	Change to the invented name of the product in Cyprus, Malta, Slovakia and Sweden.
12 February 2014	Addition of a new specification parameter.
12 February 2014	Deletion of a non-significant specification parameter.