Veterinary Medicines Directorate

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Post Authorisation Assessments

Noroseal 2.6g Intramammary Suspension for Cattle

Vm 02000/4361

•	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.