Veterinary Medicines Directorate

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Post Authorisation Assessments

Sureseal 2.6 g Intramammary Suspension for Cattle

Vm 02000/4362

•	17 July 2024	Addition of acute mastitis as a very rarely reported event and highlighting of need to follow aseptic administration technique.
•	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)
•	05 December 2023	Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product.
•	23 November 2023	Introduction of a summary of the PSMF. (NI)
•	01 November 2023	Minor changes to an approved test procedure for the finished product. (GB)
•	01 November 2023	Minor changes to an approved test procedure for the finished product. (NI)
•	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.
•	25 November 2021	Change in name of site of sterilisation.
•	April 2021	Minor changes to an approved test procedure of the finished product.
•	08 December 2020	Change in the invented name of the veterinary medicinal product from 'Cepralock 2.6g Intramammary Suspension for Cattle' to 'Sureseal 2.6g Intramammary Suspension for Cattle' in the UK only.
•	20 October 2020	Change in Distributor from: MSD Animal Health UK Ltd, Walton Manor, Walton, Milton Keynes, MK7 7AJ, United Kingdom to: Norbrook Laboratories (GB) Limited, 1 Saxon Way East, Oakley Hay Industrial Estate, Corby, Northamptonshire, NN18 9EX, United Kingdom
•	29 July 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.

•	10 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.
•	29 January 2019	Changes to the labelling and package leaflet.
•	09 October 2018	Addition of a manufacturing site of the finished product
•	02 October 2018	Change in manufacturing batch size
•	25 September 2018	Renewal – UK as RMS.
•	02 April 2015	Addition of a wipe as product packaging. Minor change to the SPC and product literature to remove a statement.
•	25 September 2014	Change of QPPV and update to the DDPS.
•	15 August 2014	Change in the specification parameters of the immediate packaging of the finished product. Addition of an in-process test applied during the manufacture of the finished product. Change in batch size of the finished product. Addition of a site of manufacture. To add additional storage precautions to the SPC and package leaflet.
•	04 June 2014	Change to the product's name in the UK, from 'Sureseal 2.6 g Intramammary Suspension for Cattle' to 'Cepralock 2.6g Intramammary Suspension for Cattle'. Change to the product's name in Sweden, from 'Noroseal 2.6 g Intramammary Suspension for Cattle' to 'Intraseal 2.6g Intramammary Suspension for Cattle'.
•	03 June 2014	Change of distributor.
•	12 February 2014	Addition of a new specification parameter.
•	12 February 2014	Deletion of a non-significant specification parameter.