



Post Authorisation Assessments

Cepritect 250 mg Intramammary Suspension for Dry Cows

Vm 02000/4423

•	23 November 2023	Introduction of a summary of the PSMF. (NI)
•	12 June 2023	Deletion of - a non-significant specification parameter of an active substance. (NI)
•	15 March 2023	Deletion of a non-signification specification parameter for the active substance. (GB)
•	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.
•	06 May 2022	Renewal.
•	08 March 2022	Variation to update the ASMF.
•	25 November 2021	Change in name of site of sterilisation.
•	05 October 2021	Minor changes to an approved test procedure 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.
•	26 July 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	20 November 2018	Change in RMS from UK to IE.
•	09 November 2018	Change in the name of a manufacturer used in the manufacture of the active substance.
•	19 June 2018	Increase in the shelf-life of the finished product as packaged for sale, from 1 year to 2 years. Change in storage conditions of the finished product.
•	28 March 2018	Change the invented name of the veterinary medicinal product from 'Cepritect 250 mg Intramammary Suspension for Dry Cows' to 'Stapenor DCef 250 mg Intramammary Suspension for Dry Cows', in Germany only.