Veterinary Medicines Directorate

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Post Authorisation Assessments

Multiject IMM Intramammary Suspension

Vm 02000/4062

•	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.
•	07 April 2021	Deletion of a non-significant in-process test applied during the manufacture of the finished product Increase in batch size of the finished product. Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions. Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions. Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions. Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions. Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions.
•	December 2020	Addition of a manufacturer of the active substance.
•	10 September 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	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.

•	16 February 2016	Update of the test procedure to comply with the updated general Ph. Eur monograph
•	10 November 2014	Change to an existing pharmacovigilance system as described in the DDPS.
•	21 March 2012	Change to distributor details.
•	20 January 2009	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance
•	11 June 2008	Changes to the SPC and Product Literature to bring in line with new legislation
•	20 February 2007	Change of legal category from POM to POM-V
•	13 October 2006	Renewal Addition of a manufacturer of an active substance Submission of a new Ph. Eur. Certificate of Suitability for an active substance
•	25 June 2004	Change of manufacturer of an active substance
•	04 June 2004	Addition of a manufacturer of an active substance
•	02 April 2004	Renewal
•	27 January 2004	Renewal
•	24 February 2003	Change to closure system