



Post Authorisation Assessments

Lincoject 10% w/v Solution for Injection

Vm 02000/4183

•	May 2024	Submission of updated CEP for the manufacture of an active substance.
•	28 April 2024	Change in test procedures for the finished product.
•	28 April 2024	Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible.
•	14 March 2024	Deletion of a non-significant specification parameter in the specification parameters or limits of the finished product.
•	14 April 2023	Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible.
•	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.
•	27 April 2022	Change to part of the (primary) packaging material not in contact with the finished product formulation. Deletion of a pack size(s) of the finished product. Update of the test procedure to comply with the updated general Ph. Eur monograph. Change in shape or dimensions of the container or closure (immediate packaging).
•	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.
•	14 March 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	09 May 2018	Update of the test procedure to comply with the updated general Ph. Eur monograph.
•	14 July 2015	Submission of a new certificate of suitability from a new manufacturer.
•	03 April 2012	Variation to change the address of a Distributor.
•	22 September 2009	Addition of a site of Assembly.
•	13 November 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	20 February 2007	Variation to change the legal category from POM to

		POM-V.
•	17 November 2006	Renewal.
•	01 November 2006	Extension of the product withdrawal period.
•	20 November 2001	New Marketing Authorisation.