



Post Authorisation Assessments

Molemec Injection for Cattle and Sheep 10 mg/ml Solution for Injection for Cattle, Sheep and Pigs Vm 02000/4261

09 March 2026	Change in the name of the veterinary medicinal product from Paramectin Multi Injection 1% w/v Solution for Injection for Cattle, Sheep and Pigs. To Molemec Injection for Cattle and Sheep 10 mg/ml Solution for Injection for Cattle, Sheep and Pigs.
07 August 2025	Change of Distributor details, from Norbrook Laboratories Ltd, Station Works, Newry, BT35 6JP Co. Down, Northern Ireland to Mole Valley Farmers Limited, Exmoor House Lime Way, Pathfields Business Park, South Molton, Devon, EX36 3LH, England.
25 August 2023	Deletion of a non-significant specification method. Editorial changes to Part II of the dossier. Minor changes to an approved test procedure for the finished product.
09 March 2023	Change in any part of the primary packaging material not in contact with the finished product formulation.
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 August 2022	Deletion of certificates of suitability for an active substance.
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 May 2018	Change of specification(s) of a former non Pharmacopoeial excipient to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State. Change of specification(s) of a former non Pharmacopoeial excipient to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State.
28 February 2018	Change to part of the (primary) packaging material not in contact with the finished product formulation.
07 February 2017	Update of the test procedure to comply with the updated general Ph. Eur monograph.

	Tightening of specification limits of the finished product Deletion of a non-significant specification parameter of the finished product
13 December 2012	Submission of new Certificates of Suitability for the active substance.
03 February 2011	Renewal Marketing Authorisation.
13 January 2010	To increase the withdrawal period of cattle from 35 days to 49 days.
29 April 2009	Correction/ simple text layout changes to SPC or product literature
25 November 2006	Replace/add manufacturing site: secondary manufacturing site for all pharm forms