



Post Authorisation Assessments

Paramectin 0.5% w/v Pour-on Solution Vm 02000/4197

•	21 March 2023	Dimensions of the new 1 L container closure of a non-sterile finished product. Change in dimensions of a container of a non-sterile finished product. Change in dimensions of a container of a non-sterile finished product.
•	09 March 2023	Editorial changes to part 2 of the dossier. Editorial changes to part 2 of the dossier.
•	01 March 2023	Addition of a new 1 L spot-on presentation for the finished product.
•	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.
•	02 August 2022	Deletion of certificates of suitability for an active substance.
•	06 May 2022	Change(s) in the SPC, labelling or package leaflet intended to implement the outcome of pharmacovigilance assessment.
•	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.
•	28 June 2019	Increase in the shelf-life of the finished product as packaged for sale, from 1 year to 2 years.
•	21 November 2018	Change in the specification parameters and limits of an excipient.
•	02 August 2018	Change in shape or dimensions of the container or closure (immediate packaging)
•	12 June 2017	Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product.
•	21 November 2016	Changes to a test procedure (including replacement or addition)
•	21 August 2015	Submission of an updated certificate of suitability.
•	11 December 2012	Variation concerning the submission of two new and one

		updated Ph. Eur. Certificate of Suitability.
•	17 December 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	24 July 2007	Renewal.
•	28 February 2007	Change of the legal category from PML to POM-VPS.
•	27 July 2006	Change in shape and dimensions of the product container.
•	23 November 2005	Addition of a site of secondary assembly.
•	12 March 2001	New Marketing Authorisation.