



Post Authorisation Assessments

Tauramox 5 mg/ml Pour-On Solution for Cattle

Vm 02000/4406

•	23 January 2024	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex (NI)
•	05 July 2023	Submission of an updated certificate of suitability (NI only).
•	29 March 2023	Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability (GB only).
•	10 February 2023	Updates to the Section 4.5 and 4.6 of the SPC and Section 6 of the PL.
•	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.
•	14 March 2022	Renewal
•	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.
•	27 February 2019	Change in RMS from UK to IE.
•	22 May 2018	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	22 March 2018	Changes to the SPC/product labelling/package leaflet following an Article 35 referral.