



Post Authorisation Assessments

Taurador 5 mg/ml Pour-on Solution for Cattle Vm 02000/4358

•	March 2024	Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product. (GB) Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product. (GB)
•	13 March 2024	Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. (GB)
•	23 November 2023	Introduction of a summary of the PSMF. (NI)
•	07 July 2023	Deletion of a non-significant specification parameter of the active substance.
•	20 February 2023	Addition of a new specification parameter of an active substance to the specification with its corresponding test method. Addition of a new specification parameter of an active substance to the specification with its corresponding test method. Addition of a new specification parameter of an active substance to the specification with its corresponding test method. Tightening of specification limits of an active substance. Tightening of specification limits of an active substance. Deletion of a non-significant specification parameter of an active substance.
•	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.
•	29 October 2021	Minor changes to an approved test procedure of the finished product.
•	06 July 2020	Change in shape or dimensions of the container or closure (immediate packaging). Tightening of specification limits of an excipient. Addition of a new specification parameter to the specification with its corresponding test method of an excipient. Deletion of a non-significant specification parameter of an excipient.
•	26 June 2019	Addition of a manufacturer responsible for batch release

		of the finished product.
•	26 June 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 March 2019	Addition of a manufacturer of the active substance.
•	21 March 2019	Change in RMS from UK to IE.
•	19 February 2019	Renewal - UK as RMS.
•	31 May 2018	Changes to the labelling and package leaflet.
•	25 September 2014	Change of QPPV and update to the DDPS.