



Post Authorisation Assessments

Triclafas Drench 5% w/v Oral Suspension

Vm 02000/4247

•	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.
•	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.
•	19 December 2017	Update of a test procedure to comply with the updated Ph. Eur. monograph. Change in test procedure to reflect compliance with the Ph. Eur. and remove reference to outdated internal test methods and test method numbers.
•	24 June 2014	Addition of a new manufacturer of the active substance.
•	25 March 2013	Change in the SPC and labelling following a procedure in accordance with articles 30 or 31 of Directive 2001/83/EC or articles 34 or 35 of directive 2001/82/EC.
•	23 November 2010	Renewal.
•	15 June 2010	To add the statement 'Do not mix with other products' to the product literature and under section 4.9 of the SPC.
•	25 October 2007	To update the SPC and the product literature in accordance with the new format.