



Post Authorisation Assessments

Trodax 34% w/v Solution for Injection

Vm 08327/4187

•	06 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
•	18 December 2020	Changes to a test procedure for the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product.
•	26 August 2020	Tightening of specification limits of an active substance used in the manufacturing process of the active substance. Addition of a new specification parameter with its corresponding test method of an active substance used in the manufacturing process of the active substance. Changes to a test procedure (including replacement) for the active substance. Changes to a test procedure (including replacement) for the active substance. Tightening of specification limits of an active substance used in the manufacturing process of the active substance. Addition of a manufacturer of the active substance.
•	28 May 2020	Change in the name and address of a manufacturer of the finished product, also responsible for batch release.
•	29 November 2018	Change in the name and address of the marketing authorisation holder from Merial Animal Health Ltd, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex, CM19 5TG to Boehringer Ingelheim Animal Health UK Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS.
•	20 November 2018	Changes to the labelling and/or package leaflet.
•	17 October 2013	Deletion of dogs as a target species as well as other significant modifications to the SPC.
•	14 October 2013	Change in the test procedure for the finished product.
•	01 May 2013	Variation to implement CVMP recommendations following an Article 35 Referral procedure. Correction to the SPC and Product Literature.
•	15 July 2010	Variation to change the SPC following formal advice received from the VMD.
•	15 July 2010	Renewal.
•	13 November 2007	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	14 December 2006	Variation to register an additional bottle size.

•	12 July 2006	Grouped variation to make changes to the SPC and outer packaging. Transfer of the legal category from PML to POM-VPS.
•	13 September 2005	Reviewed Marketing Authorisation.