



Post Authorisation Assessments

Tuloxin 100 mg/ml Solution for Injection for Cattle, Pigs and Sheep Vm 01656/5074

• 06 July 2023	Unlimited renewal
• 04 July 2023	Change in test procedure for the finished product to comply with Ph. Eur. (NI)
• 12 April 2023	Change in test procedure for the finished product to comply with Ph. Eur.
• 09 November 2021	Change in the SPC, labelling or package leaflet following assessment of the same change for the reference product.
• 17 February 2021	Tightening of specification limits of an active substance used in the manufacturing process of the active substance.
• 19 August 2020	Minor changes to an approved test procedure of the finished product
• 24 September 2019	Increase in the shelf-life of the finished product as packaged for sale, from 2 years to 3 years.