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Post Authorisation Assessments

Tulaxa 100 mg/ml Solution for Injection for Cattle, Pigs and Sheep $$\rm Vm\ 01656/5073$

•	04 July 2023	Change in test procedure for the finished product to comply with Ph. Eur. (NI)
•	16 June 2023	Unlimited renewal
•	14 April 2023	Change in test procedure for the finished product to comply with Ph. Eur.
•	20 October 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 24 months to 36 months.