



Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021, please refer to the [EMA](#) website.

Tulaven 100 mg/ml Solution for Injection for Cattle, Pigs and Sheep Vm 15052/5018

• 17 July 2024	Editorial changes to part 2 of the dossier.
• 21 June 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
• 20 September 2023	Change in test procedure for the finished product: - Other changes. Corrective factor for unspecified impurities has been included. Introduction of an additional active substance manufacturer supported by an ASMF.
• 13 December 2022	Change in manufacturing process of finished product. Addition of a manufacturing site for part or all of the manufacturing process of the finished product: - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging. Addition of a manufacturing site for part or all of the manufacturing process of the finished product: - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging.
• 19 October 2022	Change in the address of the MAH from Unit 3 Anglo Office Park, White Lion Road Amersham, Buckinghamshire HP7 9FB to Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH, United Kingdom.
• 26 January 2022	Increase in the shelf-life of the finished product as packaged for sale, from 2 to 3 years.
• 13 January 2022	Change in the SPC, labelling or package leaflet following assessment of the same change for the reference product.
• 06 July 2021	Extension of a re-test period of the active substance. Minor change to the restricted part of an Active Substance Master File. Minor change to the restricted part of an Active Substance Master File. Minor change to the restricted part of an Active Substance Master File. Minor change to the restricted part of an Active Substance Master File. Minor change to the restricted part of an Active Substance Master File.
• 20 May 2021	Change in the specification parameters and/or limits of the finished product.
• 20 May 2021	Minor changes to an approved test procedure of the finished product

