Veterinary Medicines Directorate
Woodham Lane, New Haw, Addlestone, Surrey, KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021, please refer to the EMA website.

Tulaven 25 mg/ml Solution for Injection for Pigs

Vm 15052/5019

•	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.
•	01 March 2022	Increase in the shelf-life of the finished product as packaged for sale, from 2 years 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	Minor changes to an approved test procedure of the finished product