



Post Authorisation Assessments

Tulaject 100 mg/ml Solution for Injection for Cattle, Pigs and Sheep Vm 61503/5001

13 May 2026	Introduction of a summary of the PSMF.
09 February 2026	Change in any part of the primary packaging material not in contact with the finished product formulation.
20 November 2025	Change of legal entity of the Marketing Authorisation Holder from Alivira Animal Health UK Ltd, Hygeia Building, Rear Ground Floor, 66-68, College Road, Harrow, Middlesex, HA1 1BE, United Kingdom to Alivira Animal Health Limited, 2nd Floor, 1-2 Victoria Buildings, Haddington Road, Dublin, D04 XN32, Ireland.
30 October 2025	Alignment of the product information with the latest version of the QRD template.
19 September 2025	Change to batch control arrangements and quality testing replacement of a site for a finished product. Replacement of a manufacturer responsible for batch release not including batch control or testing of a sterile or non-sterile finished product.
19 September 2025	Change in the specification parameters and/or limits of the finished product: - Other changes Replacement of a manufacturing site for part or all of the manufacturing process of the finished product. Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacture.
25 August 2023	Addition of a secondary packaging site of a finished product.
28 July 2023	Introduction of a manufacturer of the active substance supported by an ASMF.
05 August 2022	Extension of shelf-life of the finished product as packaged for sale.
27 June 2022	Change in specification parameter of the finished product.
19 November 2021	Change in the SPC, labelling or package leaflet following assessment of the same change for the reference product.
20 May 2021	Change in the invented name of the veterinary medicinal product from Tulazzin 100 mg/ml solution for cattle, pigs and sheep to Tulaject 100 mg/ml Solution for Injection for Cattle, Pigs and Sheep.
17 February 2021	Change in distributor details from Skans Healthcare Limited, 222 Mountbatten Close, Ashton-on-Ribble, Preston, PR2 2XF, United Kingdom to Vetsonic (UK) Ltd

	<p>Riccal Drive, York Road Business Park, Malton, North Yorkshire, YO17 6YE.</p> <p>Change of MAH from Skans Healthcare Limited, 222 Mountbatten Close, Ashton-on-Ribble, Preston, PR2 2XF, United Kingdom to Alivira Animal Health UK Ltd., Hygeia Building, Rear Ground Floor, 66-68 College Road, Harrow, Middlesex, HA1 1BE, United Kingdom.</p>
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