



Post Authorisation Assessments

Macrosyn 100 mg/ml Solution for Injection for Cattle, Pigs and Sheep Vm 50146/4042

•	09 January 2023	Minor change in the manufacturing process.
•	13 April 2022	Change to part of the (primary) packaging material not in contact with the finished product formulation.
•	23 December 2021	Change in the SPC, labelling or package leaflet following assessment of the same change for the reference product.
•	18 March 2021	Replacement of a secondary packaging site of the finished product.
•	26 January 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	02 December 2020	Changes to the labelling and package leaflet.
•	07 October 2020	Change of MAH, from Triveritas Ltd, Bank Barn, How Mill, Brampton, Cumbria, CA8 9JY, United Kingdom to Bimeda Animal Health Limited, 2, 3, 4 Airton Close, Tallaght, Dublin 24, IE-D24 E032, Ireland.