



Post Authorisation Assessments

Novamune Concentrate and Solvent for Suspension for Injection for Chickens Vm 15052/3000

•	19 December 2023	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
•	07 March 2023	Unlimited renewal.
•	31 January 2023	Addition of a secondary packaging site for the finished product.
•	21 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.
•	12 April 2022	Minor change in the manufacturing process of the active substance.
•	17 September 2021	Change in the specification limits of the finished product.
•	19 May 2020	Minor change to an approved test procedure for an excipient. Addition to a test procedure for an excipient. Change in the composition (excipients) of the finished product.
•	15 January 2020	Change in shape or dimensions of the container or closure (immediate packaging) Change in the manufacturing process of the finished product Reduction of the shelf life of the finished product as packaged for sale from 3 years to 30 months (solvent) Change to in-process tests or limits applied during the manufacture of the finished product Change in the specification limits of the finished product
•	15 January 2020	Change of the invented name of solvent
•	26 March 2019	Change in RMS from UK to ES.