



Post Authorisation Assessments

Novamune Concentrate and Solvent for Suspension for Injection for Chickens

•	22 March 2022	Minor change in the manufacturing process of the active substance.
•	17 February 2022	Changes to the package leaflet.
•	July 2021	Change in the fill volume 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.