



## Post Authorisation Assessments

### Novomate 277.8 mg/ml Powder and Solvent for Suspension for Injection for Cattle Vm 52429/4000

•	07 June 2021	Renewal – UK as CMS.
•	19 February 2021	Change in distributor details. From Virbac Ltd, Woolpit Business Park, Windmill Avenue, Woolpit, Bury St Edmunds, Suffolk, IP30 9UP to Huvepharma EOOD, Este Offices Bldg.3A, Nikolay Haytov Street, 1113 Sofia, Bulgaria.
•	22 December 2020	Change in the invented name of the veterinary medicinal product from Penethamate Pharmanovo 214,5 mg/ml poudre et solvant pour suspension injectable pour bovins to LohMastite 214,5 mg/ml poudre et solvant pour suspension injectable pour bovins in FR.
•	30 October 2020	Replacement of a manufacturer responsible for batch release including batch control/testing. Addition of a secondary packaging site of the finished product. Addition of a manufacturing site of the finished product.
•	07 October 2020	Update to the AMSF.
•	04 August 2020	Introduction of a new pharmacovigilance system.
•	15 January 2020	Change of MAH, from Pharmanovo Veterinararzneimittel GmbH, Liebochstrasse 9, A-8143 Dobl, Austria to Lohmann Pharma Herstellung GmbH, Heinz - Lohmann - Strasse 5, 27472 Cuxhaven, Germany.
•	02 April 2019	Update of the quality dossier.
•	21 March 2019	Change in RMS from UK to IE.
•	07 December 2018	Change in the name and address of the marketing authorisation holder from Pharmanovo GmbH, Sudetenstrasse 19, 30559 Hannover, Germany to Pharmanovo Veterinärarzneimittel GmbH, Liebochstrasse 9, 8143 Dobl, Austria.
•	15 May 2017	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	29 December 2016	Changes to the milk withdrawal period of the veterinary medicinal product. From 108 to 96 hours.