Veterinary Medicines Directorate

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Post Authorisation Assessments

Norotril Max 100 mg/ml Solution for Injection for Cattle

•	16 September 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	29 August 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	30 July 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	20 November 2018	Change in RMS from UK to IE.
•	19 November 2018	Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product.
•	15 August 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer
•	27 October 2015	Renewal – UK RMS
•	22 January 2015	Submission of a new Ph. Eur Certificate of Suitability for the active substance.
•	25 September 2014	Change of QPPV and update to the DDPS.
•	06 February 2014	Submission of an updated Certificate of Suitability for the active substance.
•	29 May 2012	Change of Distributor.
•	12 July 2011	To change the name of the medicinal product in France only.
•	22 October 2010	Changes to therapeutic indication.