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Post Authorisation Assessments

Norbonex 5 mg/ml Pour-on Solution for Beef and Dairy Cattle

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•	12 November 2021	Change in control of the finished product.
•	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.
•	21 June 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	27 February 2019	Change in RMS from UK to DE.
•	01 March 2018	Renewal – UK as RMS
•	8 June 2016	Changes in the manufacturing process of the active substance (Update to ASMF).
•	25 September 2014	Change of QPPV and update to the DDPS.
•	04 June 2014	Change to the invented name of the product in Germany only.
•	04 June 2014	Extension of shelf life of the finished product as packaged for sale from 18 months to 24 months.