



## Post Authorisation Assessments

### Norocillin 30% w/v Suspension for Injection

•	14 January 2020	Changes to SPC & product literature following a periodic safety update report. (PSUR).
•	21 April 2020	Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions.
•	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.
•	16 April 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	18 October 2018	Reduction of the shelf life of the finished product as packaged for sale from 2 years to 1 year for glass vials.
•	16 July 2018	Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions.
•	23 May 2018	Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product.
•	09 February 2017	Addition of a manufacturer of the active substance.
•	30 October 2014	Addition of an active substance manufacturer.
•	23 April 2014	Change of distributor.
•	20 December 2013	Change to the immediate packaging of the finished product and change to the pack size of the finished product.
•	03 December 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	02 November 2007	Renewal.
•	28 February 2007	Transfer of the legal category from POM to POM-V.
•	10 November 2005	Addition of a site of assembly.
•	25 July 2005	Change of the name of the Active Substance Manufacturer.
•	04 June 2004	Extension of a withdrawal period.
•	06 November 2003	Renewal.
•	28 May 2003	Extension of a withdrawal period.
•	28 May 2003	Extension of a withdrawal period.

•	28 May 2003	Extension of a withdrawal period.
•	21 March 2002	Addition of an Active Substance Manufacturer.
•	12 June 2000	Increase in batch size.
•	09 June 1999	Variation concerning shelf life.