



Post Authorisation Assessments

Norocarp 50mg/ml Solution for Injection for Cattle and Horses

•	March 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	22 November 2019	Submission of a new Ph. Eur. certificate of suitability for an active substance excipient from a new 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.
•	21 May 2019	Change in the manufacturer of a starting material used in the manufacturing process of the active substance.
•	07 July 2017	Changes in the composition (excipients) of the finished product.
•	05 August 2015	Change in test procedure for the finished product
•	28 February 2014	Renewal of Marketing Authorisation.
•	11 April 2012	Change of distributor.