



Post Authorisation Assessments

Noroclav 50 mg Tablets for Dogs and Cats

Vm 02000/5010

•	May 2024	New CEP submitted for the manufacture of an active substance.
•	25 April 2024	Minor change to the method of analysis for Potentiated Penicillin 50 mg Tablets. Minor change to the determination of the Total Aerobic Microbial Count, the Total Combined Yeast and Mould Count and an Absence of Escherichia coli in 1 gram for the finished product.
•	27 September 2023	Change in the shelf-life or storage conditions of the finished product.
•	28 October 2022	Change in distributor details from Norbrook Laboratories (GB) Ltd, 1 Saxon Way East, Oakley Hay Industrial Estate, Corby, Northamptonshire, NN18 9EX, United Kingdom to Norbrook Laboratories Limited, Carnbane Industrial Estate, Newry, Co Down, BT35 6QQ, Northern Ireland.
•	06 January 2022	Deletion of a non-significant specification parameter of an excipient.
•	19 November 2019	Addition of a secondary packaging site of the finished product. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	16 September 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	01 August 2019	Qualitative and/or quantitative changes to the excipients. Minor change in the manufacturing process of an immediate release solid oral dosage form.
•	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.
•	14 January 2019	Update of the test procedure to comply with the updated general Ph. Eur monograph. Changes to a test procedure for the finished product.
•	02 November 2018	Change in RMS from UK to IE.
•	23 March 2016	Submission of a new or updated Ph. Eur. certificate of suitability Submission of a new or updated Ph. Eur. certificate of suitability Submission of a new or updated Ph. Eur. certificate of

		suitability Deletion of a Ph. Eur. certificate of suitability Deletion of a Ph. Eur. certificate of suitability Submission of a new or updated Ph. Eur. certificate of suitability
•	28 November 2014	Update to the DDPS.
•	03 January 2014	Submission of an updated Ph. Eur. Certificate of Suitability for an already approved manufacturer of the active substance.
•	17 January 2012	Change of distributor address.
•	27 April 2011	Variation to remove an Active Substance Manufacturer.
•	24 August 2009	Renewal.
•	25 April 2008	Extension of shelf life.
•	09 April 2008	Change in composition of the immediate packaging.
•	23 August 2007	Change in the name of the medicinal product.
•	17 April 2007	Addition of an Active Substance Manufacturer.
•	07 February 2007	Transfer of legal category from POM to POM-V.
•	24 January 2007	Addition of a target species.
•	30 September 2005	Extension of product shelf life.
•	15 April 2004	Mutual Recognition Procedure.
•	24 June 2003	Variation concerning Certificate of Suitability revisions.
•	18 June 2003	Variation to update Labelling.
•	24 January 2003	Additional Presentation.
•	08 April 2002	New Marketing Authorisation.