Veterinary Medicines Directorate

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Post Authorisation Assessments

Noroclav 50 mg Tablets for Dogs and Cats

Vm 02000/5010

•	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.