Veterinary Medicines Directorate

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Post Authorisation Assessments

Noroclav 250 mg Tablets for Dogs

Vm 02000/5012

•	May 2024	New CEP submitted for the manufacture of an active substance.
•	28 April 2024	Minor change in the test procedure for 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.
•	23 November 2023	Introduction of a summary of the PSMF. (NI)
•	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 active substance manufacturer.
•	24 November 2011	Variation to update total excipient content on the SPC and QRD.
•	24 November 2011	Changes in pack size of the finished product.
•	02 November 2011	Change in Distributor details.
•	27 April 2011	Deletion of a manufacturing site.
•	21 August 2009	Renewal.
•	25 April 2008	Increase in shelf life of finished product.
•	09 April 2008	Change in composition of the immediate packaging.
•	23 August 2007	Change in the name of the product.
•	17 April 2007	Addition of an Active Substance Manufacturer.
•	20 February 2007	Corrections to the SPC and Product Literature.
•	07 February 2007	Tranfer of legal category from POM to POM-V.
•	28 November 2005	Extension of shelf-life of the finished product.
•	15 April 2004	Mutual Recognition Procedure.
•	24 June 2003	Variation concerning revisions of Certificates of Suitability.
•	18 June 2003	Variation to update Labelling.
•	28 January 2003	Additional Presentation.
•	08 March 2002	New Marketing Authorisation.