Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Noroclav 500 mg Palatable Tablets for Dogs

Vm 02000/4259

•	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.
•	19 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.
•	31 December 2018	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.
•	31 March 2016	Submission of new or updated Ph. Eur. certificates of suitability Deletion of Ph. Eur. certificates of suitability
•	28 November 2014	Update to the DDPS.
•	07 March 2013	Submission of updated Ph. Eur. Certificates of Suitability for an already approved manufacturer. Deletion of an active ingredient manufacturing site.
•	11 October 2012	To add the total content for colouring agent Lake Carmosine (2.45 mg/tablet) to the SPC and Product Literature.
•	02 November 2011	To change the distributor.
•	13 May 2011	Renewal – UK as RMS.
•	23 October 2008	New/updates Ph. Eur. Certificate of Suitability for active/active component: new manufacturer (other).
•	12 October 2007	New MA.
•	22 May 2006	Change in pack size of the finished product.