Veterinary Medicines Directorate

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Post Authorisation Assessments

Noropraz, 18.7 mg/g + 140.3 mg/g Oral Paste for Horses

Vm 02000/4365

•	02 June 2023	Change in dimensions of the container or closure of a non-sterile finished product. Change in dimensions of the container or closure of a non-sterile finished product.
•	24 February 2023	Deletion of a manufacturing site for an active substance. Minor changes to an approved test procedure for the finished product.
•	01 November 2022	Updated certificate of suitability from an already approved manufacturer. Updated certificate of suitability from an already approved manufacturer.
•	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
•	05 October 2022	Deletion of a manufacturing site for an active substance. Minor changes to an approved test procedure for the finished product.
•	27 October 2020	Addition of a secondary packaging site of the finished product.
•	20 December 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved 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.
•	31 July 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	18 October 2018	Renewal – UK as CMS
•	07 February 2018	Deletion of manufacturing site for an active substance.
•	11 April 2017	Submission of a new certificate of suitability. Submission of a new certificate of suitability.
•	12 August 2015	Submission of an updated certificate of suitability
•	29 August 2014	Changes to the DDPS.

•	12 June 2014	Submission of an updated Ph. Eur certificate of suitability.
•	16 May 2014	Change to the invented name of the medicinal product in Estonia, Latvia, Lithuania, Norway, Sweden and Denmark.