



Post Authorisation Assessments

Peptizole 370 mg/g Oral Paste for Horses Vm 02000/4389

•	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.
•	22 December 2021	Change in the SPC, labelling or package leaflet following assessment of the same change for the reference product.
•	27 October 2020	Addition of a secondary packaging site of the finished product.
•	08 August 2019	Update of the test procedure to comply with the updated general Ph. Eur monograph.
•	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.
•	22 August 2018	Renewal UK as CMS
•	05 January 2018	Repeat Use application to add 1 new member state (administrative procedure completed in 1 day by RMS)
•	11 May 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance manufacturer
•	15 July 2015	Change to the product name in Sweden only.
•	20 February 2015	Change in the finished product specification for the active substance.
•	17 February 2015	Change in test procedure for the finished product.
•	29 August 2014	Changes to the DDPS.
•	08 May 2014	Change of invented product name in Hungary, Spain, Italy, Czech Republic, Poland and Sweden.
•	10 April 2014	Extension to the shelf life of the finished product as packaged for sale to 24 months.