Veterinary Medicines Directorate

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Post Authorisation Assessments

Ulcergold 370 mg/g Oral Paste for Horses

Vm 02000/4390

•	02 January 2024	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
•	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.
•	30 January 2019	Change in the invented name of the veterinary medicinal product from Ulcergold to Equinor in France only.
•	07 September 2018	Renewal – UK as CMS.
•	11 May 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance manufacturer
•	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.
•	14 April 2014	Change in the invented name of the veterinary medicinal product.
•	10 April 2014	Change in shelf life of the finished product.