



Post Authorisation Assessments

Copinox Ewe/Calf 4g Capsule, Hard Vm 14016/4001

•	22 July 2022	Change in excipient content of capsule.
•	18 September 2020	Submission of an updated Ph. Eur. TSE certificate of suitability for an excipient from an already approved manufacturer. Submission of an updated Ph. Eur. TSE certificate of suitability for an excipient from an already approved manufacturer. Submission of an updated Ph. Eur. TSE certificate of suitability for an excipient from an already approved manufacturer. Deletion of Ph. Eur. TSE certificates of suitability for an excipient.
•	14 June 2018	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product for solid pharmaceutical forms.
•	31 May 2018	Replacement of components of the colouring system of the finished product.
•	25 October 2017	Deletion of Ph. Eur. certificates of suitability for an excipient. Submission of a new Ph. Eur. certificate of suitability for an excipient.
•	30 August 2017	Submission of a new Ph. Eur. TSE certificate of suitability for a starting material from an already approved manufacturer. Submission of an updated Ph. Eur. TSE certificate of suitability for a starting material from an already approved manufacturer.
•	05 December 2012	Addition of a safety warning regarding copper poisoning in a specific breed
•	18 January 2012	Submission of Ph. Eur. TSE Certificates of Suitability for excipients
•	28 July 2010	Minor changes to the SPC and Product Literature
•	21 July 2010	Submission of Ph. Eur. TSE Certificates of Suitability for excipients
•	09 December 2009	Submission of updated EDQM certificates for capsules
•	20 November 2008	Change of legal category from GSL to AVM-GSL Changes t the SPC and Product Literature to bring in line with new legislation
•	18 November 2005	Renewal
•	26 October 2001	Change of distributor

