



## Post Authorisation Assessments

### Copinox Lamb 2g Capsule, Hard Vm 14016/4002

•	08 April 2024	Change in the specification parameters or limits of the finished product to describe the appearance of the product more accurately. Deletion of a non-significant specification parameter of the finished product ore accurately.
•	03 April 2024	Removal of titanium dioxide colourant from the capsule as titanium dioxide has been withdrawn from the EU and UK feed list.
•	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.
•	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 safety warning regarding copper poisoning of a specific breed
•	18 January 2012	Submission of updated Ph. Eur. Certificated 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 to the SPC and Product Literature to bring in line with new legislation
•	18 November 2005	Renewal
•	07 November 2001	Change of distributor