



Post Authorisation Assessments

Clavaseptin 250 mg Palatable Tablets for Dogs Vm 06462/3000

| | |
|-------------------|--|
| 22 February 2026 | Submission of a Ph. Eur. CEP for an active substance. |
| 25 July 2025 | Change in legal entity of MA holder from Vetoquinol UK Limited, Steadings Barn, Pury Hill Business Park, Nr. Alderton, Towcester, Northamptonshire, NN12 7LS to Vetoquinol SA, 34 Rue de Chene Sainte-Anne, Magny-Vernois, 70200 Lure, France. |
| 25 June 2025 | Additional indications in dogs and cats. One-off alignment of the product information with version 9.0* of the QRD templates i.e. major update of the QRD template. |
| 09 May 2025 | Change in the specification parameters or limits of an excipient - addition of a new specification parameter to the specification with its corresponding test method. Change in the specification parameters or limits of an excipient-tightening of specification limits. Deletion of a non-significant specification parameter in the specification parameters or limits of an excipient. Minor changes to an approved test procedure for an excipient. |
| 26 February 2025 | Introduction of a retest period of the active substance where none is specified in the Ph. Eur. Certificate of Suitability. |
| 14 December 2024 | Submission of updated CEP for an active substance manufacturer. |
| 28 April 2024 | Minor changes to an approved test procedure the finished product. (NI) |
| 24 March 2023 | Minor changes to an approved test procedure the finished product. |
| 25 March 2022 | Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. |
| 23 March 2022 | Minor changes to an approved test procedure of the finished product. |
| 17 August 2020 | Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. |
| 05 February 2020 | Changes to the SPC and QRD text. |
| 06 February 2019 | Change in RMS from UK to FR. |
| 07 September 2018 | Change in the address of the marketing authorisation holder from Vétoquinol UK Limited, Vetoquinol House, Great Slade, Buckingham Industrial Park, Buckingham, MK18 1PA to Vetoquinol UK Limited, Steadings Barn, Pury Hill Business Park, Nr Alderton, Towcester, Northamptonshire, NN12 7LS. |
| 30 August 2018 | Deletion of a manufacturing site for an active substance. Deletion of a manufacturing site for an active substance. |
| 29 December 2017 | Change in the QPPV of an existing pharmacovigilance system |

| | |
|-------------------|---|
| | as described in the DDPS. |
| 30 August 2017 | Change in the address of the marketing authorisation holder in Germany from Vetoquinol GmbH, Parkstr. 10, D - 88212 Ravensburg to Vetoquinol GmbH, Reichenbachstr. 1, D-85737 Ismaning. |
| 11 May 2016 | Deletion of a manufacturing site of the active substance. Submission of an updated certificate of suitability. Submission of an updated certificate of suitability. Submission of an updated certificate of suitability. Submission of an updated certificate of suitability. |
| 30 March 2016 | Harmonisation of SPC and QRD between all CMS |
| 11 August 2015 | Changes to the labelling layout of the blister. |
| 09 April 2015 | Submission of a new Ph. Eur. Certificate of Suitability. Introduction of a re-test period for the active substance. |
| 26 November 2014 | Renewal, UK as RMS. |
| 17 April 2014 | Change in the specification parameters and limits of the finished product. Minor changes in the manufacturing process. Replacement of a site of manufacture, batch control and primary packaging. Change to in-process tests applied during the manufacture of the finished product. Change in immediate packaging of the finished product. |
| 03 June 2011 | Change of shelf life from 24 to 36 months Change in specification of the finished product Change in test procedures performed on the finished product |
| 26 May 2011 | Addition of 2 manufacturers of the active substance |
| 12 January 2011 | Changes to the SPC |
| 14 October 2010 | Repeat use |
| 23 July 2010 | Renewal |
| 03 February 2009 | Change of name of manufacturer of the finished product |
| 07 October 2005 | Decentralised procedure, UK as RMS |
| 16 December 2004 | Change of MAH address |
| 17 September 2004 | Addition of a secondary assembler of the dosage form |