Veterinary Medicines Directorate

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Post Authorisation Assessments

Clavaseptin 50 mg Palatable Tablets for Dogs and Cats

Vm 06462/3001

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, Northanmptonshire, 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 months to 36 months Change in specification of the finished product Changes to test performed on the finished product
26 May 2011	Addition of two 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 active substance
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