Veterinary Medicines Directorate

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Post Authorisation Assessments

Clavaseptin 62.5 mg Palatable Tablets for Dogs and Cats

Vm 08007/5009

04 December 2024	Submission of a new Ph. Eur. CEP from a new manufacturer for a non-sterile active substance.
23 November 2024	Submission of a new CEP for a new active substance manufacturer.
23 November 2024	Introduction of a retest period of the active substance where none is specified in the Ph. Eur. Certificate of Suitability.
14 December 2023	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
24 March 2023	Minor changes to an approved test procedure the finished product.
23 March 2022	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
08 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.
08 March 2018	Renewal – UK as RMS
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.
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.