



Post Authorisation Assessments

Clavucill 200 mg/50 mg, Tablets for Dogs

Vm 19968/4002

18 February 2026	Submission of a Ph. Eur. CEP for an active substance. Submission of a Ph. Eur. CEP for an active substance. Deletion of a manufacturer of an active substance.
18 February 2025	Change to the specification limit of a specific impurity at shelf life.
19 November 2024	Change in the address of a manufacturer of the finished product.
15 July 2022	Updated certificate of suitability for an already approved manufacture. Updated certificate of suitability for an already approved manufacture. New certificate of suitability from a new manufacturer for an active substance. New certificate of suitability from a new manufacturer for an active substance.
27 December 2018	Changes to the labelling and package leaflet.
13 November 2018	Change in distributor details from: Chenelle Animal Heath Ltd., 7 Rodney Street, Liverpool, L1 9HZ, UK, to V.M.D. n.v., Hoge Mauw 900, 2370 Arendonk, Belgium.
02 October 2018	Change in shape or dimensions of the container or closure (immediate packaging).
17 November 2016	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
30 July 2015	Introduction of a new pharmacovigilance system, which has not been assessed by the relevant NCA/EMA.
03 June 2015	Removal of cats as a target species. Change in the name of the medicinal product from Clavucill Tablets 250 mg to Clavucill 200 mg/50 mg tablets for dogs.
25 March 2015	Change to the MAH.
23 December 2014	Reduction of shelf-life of the finished product in the UK, from 3 years to 2 years.
04 December 2014	Change in the specification limits of the finished product at both release and end of shelf-life.
05 August 2014	Harmonisation of SPC and Mock-ups with Ireland.
16 June 2014	Change in the shelf life of the finished product.
28 January 2014	Submission of updated Ph. Eur. Certificates of Suitability.
04 July 2013	Renewal procedure.
19 May 2009	To update the reference number of the certificate of suitability for Potassium Clavulanate.

