Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Clavucill 200 mg/50 mg, Tablets for Dogs

Vm 19968/4002

•	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.