



Post Authorisation Assessments

Clavubactin 500/125 mg Tablets for Dogs Vm 19994/4027

•	25 April 2019	Changes to the labelling and package leaflet. Change in distributor details to Dechra Veterinary Products Limited Sansaw Business Park, Hadnall, Shrewsbury, Shropshire SY4 4AS United Kingdom. From Animalcare Ltd to Dechra Veterinary Products Limited
•	20 February 2017	Increase in the shelf-life of the finished product as packaged for sale, from 2 to 3 years.
•	22 February 2016	Renewal-UK -CMS
•	13 January 2016	Deletion of a site of manufacture. Submission of an updated certificate of suitability.
•	05 March 2015	Change of distributor. Variation to obtain joint-labelling between the UK and IE.
•	28 November 2014	Variation to change the product name in IE only from Clavoral 250/62.5 mg Tablets for Dogs to Clavubactin 250/62.5 mg Tablets for Dogs and in IS and PL from Clavubactin 250/62.5 mg Tablets for Dogs to Clavubactin vet 250/62.5 mg Tablets for Dogs.
•	26 November 2014	Deletion of manufacturer and batch release sites. Minor amendment to SPC and product literature.
•	23 September 2013	To add the following pack sizes: Carton containing 1 aluminium/aluminium blister strips each strip with 10 tablets. Carton containing 25 aluminium/aluminium blister strips each strip with 10 tablets.
•	12 July 2013	Addition of a new finished product manufacturer responsible for primary and secondary packaging, testing and batch release. Also a minor change to the manufacturing process, change to the shape of the tablet and introduction of a new tablet stamp.
•	27 April 2011	To change the name of the medicinal product from Clavoral 500/125 mg Tablets for Dogs to Clavubactin 500/125 mg Tablets for Dogs.