



Post Authorisation Assessments

Enrotron Flavour 50 mg Tablets for Dogs Vm 24745/4012

•	08 December 2020	Change to in-process tests or limits applied during the manufacture of the finished product.
•	09 January 2020	Changes to the labelling.
•	September 2017	Minor change in the manufacturing process of the finished product. Tightening of in-process limits applied during the manufacture of the finished product.
•	02 March 2017	Replacement of a manufacturing site for secondary packaging.
•	27 April 2016	Renewal – UK as CMS
•	27 April 2016	Submission of a new Ph. Eur. certificate of suitability.
•	17 September 2015	Replacement or addition of a site where batch control/testing takes place. Replacement or addition of a secondary packaging site of the finished product. Replacement or addition of a primary packaging site of the finished product. Replacement or addition of a secondary packaging site of the finished product. Replacement or addition of a manufacturing site of the finished product.
•	28 th November 2012	To change the QPPV.
•	24 th February 2011	Changes to an existing pharmacovigilance system as described in the DDPS.