Veterinary Medicines Directorate

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

Post Authorisation Assessments

Enrotron 25 mg/ml Solution for Injection for Dogs, Cats, Rodents, Reptiles and Ornamental Birds

Vm 24745/4029

•	26 January 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	26 November 2019	Introduction of a new pharmacovigilance system.
•	22 February 2019	Change of MAH from Forte Healthcare Ltd, Cougar Lane, Naul, Co. Dublin, Ireland to aniMedica GmbH, Im Südfeld 9, 48308 Senden-Bösensell, Germany.
•	09 May 2017	Renewal – UK CMS.
•	10 March 2017	Replacement of a secondary packaging site.
•	28 July 2016	Addition of a manufacturer responsible for batch release of the finished product.
•	12 July 2016	Deletion of one active substance manufacturer and introduction of a new active substance manufacturer (supported by CEP). Deletion of one finished drug product manufacturing site. Submission of a new Ph. Eur. certificate of suitability for the new active substance supplier.
•	27 February 2015	Addition of a manufacturer for the finished product, batch control and secondary packaging. Addition of a manufacturer for the finished product. To add an additional site for secondary packaging.
•	04 November 2014	Changes to SPC and product literature.
•	28 November 2013	Submission of a new updated Ph. Eur. Certificate of Suitability.
•	30 August 2013	Submission of a new updated Ph. Eur. Certificate of Suitability.