



## Post Authorisation Assessments

### Enrotron 25 mg/ml Solution for Injection for Dogs, Cats, Rodents, Reptiles and Ornamental Birds Vm 24745/4029

17 December 2025	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
12 December 2024	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance. (GB and NI).
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.