Veterinary Medicines Directorate

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Post Authorisation Assessments

Enrotron 100 mg/ml Solution for Injection for Cattle, Sheep, Goats and Pigs
Vm 24745/4028

•	03 February 2023	Change of Distributor address, from: Forte Healthcare Limited, Cougar Lane, Naul, Co. Dublin, Ireland to: Forte Healthcare Limited, Block 3, Unit 9, CityNorth Business Campus, Stamullen, Co. Meath, K32 D990, Republic of Ireland.
•	05 October 2022	Changes in the SPC and QRD to implement the outcome of a referral procedure.
•	03 March 2022	Repeat Use to add one member state
•	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 as 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 two manufacturers for the finished product, batch control and secondary packaging. 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.