Veterinary Medicines Directorate

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Post Authorisation Assessments

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

Vm 24745/5004

08 July 2026	Addition of a site of finished product manufacture.
27 October 2025	One-off alignment of the product information with version 3 of the QRD template.
26 August 2025	Minor change in the manufacturing process. Change in immediate packaging of the finished product. Change in immediate packaging of the finished product.
07 March 2025	Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product.
12 December 2024	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance (GB and NI).
27 November 2024	Change in the address of a manufacturer of the finished product (GB).
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.