



Post Authorisation Assessments

Enrodexil 100 mg/ml Solution for Injection for Cattle and Pigs Vm 36547/4003

•	18 August 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	18 September 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	18 May 2016	Renewal – UK as CMS
•	04 August 2015	Updated certificate of suitability.
•	03 November 2014	Changes to the SPC and product literature following an article 35 referral. Deletion of a manufacturing site for the finished product, secondary packaging and responsible for batch release.
•	06 November 2012	Introduction of a new pharmacovigilance system.
•	05 October 2012	Removal of a route of administration for cattle.
•	04 July 2012	Change of MAH details.
•	23 December 2011	To add a new manufacturer of the finished product.
•	23 December 2011	Change to batch release arrangements and quality control testing of the finished product.
•	09 November 2011	To change the name and address of the MAH from Romikin Farma, S.L. to Laboratorios Velvian S.L.
•	01 November 2011	To add an additional pack size.