



Post Authorisation Assessments

Enroxil 50 mg/ml Solution for Injection for Calves, Pigs and Dogs

Vm 01656/3068

•	11 May 2024	One-off alignment of the product information with version 9.0 of the EU QRD templates.
•	06 May 2020	Addition of a site where batch control/testing takes place.
•	28 April 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	15 July 2019	Update of the test procedure to comply with the updated general Ph. Eur monograph.
•	11 June 2019	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	29 January 2018	Change in RMS from UK to IE.
•	26 October 2017	Change in contact details for local representative.
•	16 December 2015	Deletion of a non-significant specification parameter of an excipient.
•	26 March 2015	Deletion of a non-significant specification parameter. Submission of new certificates of suitability.
•	19 March 2015	Deletion of a distributor.
•	29 January 2015	Update of SPC and product literature following an EU Commission decision.
•	05 November 2014	Update of SPC and product literature following EU Commission decision.
•	04 November 2013	Addition of a manufacturer responsible for batch release.
•	31 October 2013	To change the name of the veterinary medicinal products in Germany only from Enroxil 50 mg/ml injektionslösung für rinder (Kälber), Schweine und Hunde and Enroxil 100 mg/ml injektionslösung für rinder und schweine to Enroxal 50 mg/ml injektionslösung für rinder (Kälber), Schweine und Hunde and Enroxal 100 mg/ml injektionslösung für rinder und schweine.
•	01 December 2011	To add Type II amber glass vials as immediate packaging.
•	01 December 2011	To change the specification limits of the finished product.
•	19 August 2011	To change the shelf-life of the finished product as packaged for sale from 2 years to 5 years.
•	15 August 2011	To add a manufacturer of the active substance.
•	15 July 2011	To change the specification of the active substance.
•	15 July 2011	To add a new supplier for rubber stopper.
•	28 April 2011	Renewal – UK as RMS.
•	15 December 2009	To change the distributor.
•	26 August 2009	To change the Marketing Authorisation Holder.
•	19 December 2007	To change the distributor.

