Veterinary Medicines Directorate

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Post Authorisation Assessments

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

Vm 01656/3068

16 May 2026	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
28 April 2026	Change to in-process test applied during manufacture of the finished product.
23 September 2025	Change to comply with an update of the relevant monograph of the Ph. Eur. Change to comply with an update of the relevant monograph of the Ph. Eur. Deletion of - a Ph. Eur. CEP for an active substance. Submission of an updated Ph. Eur. CEP from an already approved manufacturer for an active substance.
09 January 2025	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
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.