



Post Authorisation Assessments

Enroxil Max 100 mg/ml Solution for Injection for Cattle Vm 01656/4006

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 (NI)
27 June 2024	Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State. Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State. Submission of a new Ph. Eur. CEP from a new manufacturer for a non-sterile active substance. (NI)
31 July 2023	Change to comply with Ph. Eur. Change to comply with Ph. Eur. Submission of a new Certificate of Suitability. (GB)
12 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.
23 October 2018	Update to the Local Representative details.
29 January 2018	Change in RMS from UK to IE.
28 October 2015	Change in test procedure for an excipient
10 August 2015	Changes to the labelling and package leaflet.
22 May 2015	Submission of a new and an updated Ph. Eur. Certificate of Suitability.
30 April 2015	Addition of UK local representative information to package leaflet.
16 March 2015	Deletion of a distributor.
23 April 2014	To change the name of the veterinary medicinal product in Belgium only from 'Enroxil Max 100 mg/ml solution for injection for cattle' to 'Enroxil 100 100 mg/ml solution for injection for cattle.'
15 August 2013	Change of manufacturer for the active substance.
17 January 2013	To change the shelf-life of the finished product as packaged for sale from 3 to 5 years.

04 January 2013	Addition of a supplier of packaging components. Submission of a new Ph. Eur certificate of suitability from an already approved manufacturer.
17 December 2012	Renewal procedure – UK as RMS.
01 February 2012	Changes to the route of administration.
21 April 2010	To add an additional distributor
25 February 2010	To change the shelf life from 2 years to 3 years.
16 December 2009	To add a manufacturer responsible for batch release not including batch control for the finished product
16 December 2009	To add a manufacturing site as secondary packaging site of the finished product
16 April 2009	To change the product name is Portugal and Italy.
30 September 2008	MRP – UK as RMS
31 January 2008	To add 2 Distributors