Veterinary Medicines Directorate

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Post Authorisation Assessments

Enroxil Max 100 mg/ml Solution for Injection for Cattle

Vm 01656/4006

•	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