Veterinary Medicines Directorate

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Post Authorisation Assessments

Enrox Max 100 mg/ml Solution for Injection for Cattle and Pigs

Vm 01656/5066

21 April 2026	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
20 May 2025	Submission of an updated CEP for the manufacture of an active substance.
23 April 2025	Minor change in the manufacturing process of the finished product. Change in the holding time of an intermediate or bulk product. Change to in-process tests or limits applied during the manufacture of the finished product.
21 March 2024	One-off alignment of the product information with version 9.0 of the QRD templates.
24 July 2023	Submission of a new Ph. Eur. CEP from a new manufacturer for a non-sterile: – active substance.
24 May 2023	Change to comply with an update of the relevant monograph of the Ph. Eur. Change to comply with Ph. Eur. by removing reference to the internal test method and test method number. Changes to the quality part of the dossier: Deletion of - a Ph. Eur. CEP for an active substance.
20 January 2023	Change to comply with an update of the relevant monograph of the Ph. Eur. Change to comply with Ph. Eur. by removing reference to the internal test method and test method number. Deletion of Ph.Eur CEP for an active substance.
02 March 2020	Addition of a site where batch control/testing takes place. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
26 July 2019	Update of the test procedure to comply with the updated general Ph. Eur monograph.
24 December 2018	Changes to an existing pharmacovigilance system as described in the DDPS.
17 July 2018	Renewal – UK CMS.
02 December 2015	Minor changes to an approved test procedure
29 April 2015	To add UK local representative information to package leaflet.
01 April 2015	Submission of an updated and new certificate of

	suitability.
09 December 2013	Introduction of a new pharmacovigilance system.
09 December 2013	Change of invented name of the product from ‘Enrox Max 100 mg/ml Solution for Injection’ to ‘Enroxal Max 100 mg/ml Solution for Injection’ in Germany only.
28 November 2013	Change of MA holder from Billev Pharma aps to Krka Dd.