



Post Authorisation Assessments

Emdofluxin 50 mg/ml, Solution for Injection for Cattle, Pigs and Horses Vm 34534/3000

05 September 2025	Harmonisation of the generic/hybrid product after SPC harmonisation of the reference product.
21 February 2024	One-off alignment of the product information with version 9.0* of the QRD templates.
10 March 2023	Change in the name of the marketing authorisation holder from Emdoka bvba to Emdoka. Updates to Section 4.5, 5.2 and Sections 12 and 15 of the PL.
12 April 2022	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Increase in the shelf-life of the finished product as packaged for sale, from 30 months to 36 months.
21 January 2021	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.