



Post Authorisation Assessments

Emdofluxin 50 mg/ml, Solution for Injection for Cattle, Pigs and Horses Vm 34534/5007

•	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.