



Post Authorisation Assessments

Cronyxin 50 mg/g Oral Paste for Horses Vm 50146/5004

•	28 April 2024	Unlimited renewal.
•	27 July 2023	Change in SPC, labelling or package leaflet to implement recommendation from the competent authority to add: Flunixin is toxic to avian scavengers. Do not administer to animals susceptible to enter wild fauna food chain. In case of death or sacrifice of treated animals, ensure that they are not made available to wild fauna.
•	23 June 2023	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance.
•	19 May 2023	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance.
•	16 March 2023	One-off alignment of the product information with version 9.0* of the QRD templates.
•	31 May 2022	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
•	18 March 2021	Replacement of a secondary packaging site of the finished product.
•	26 January 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	05 August 2020	Change in the specification limits of the finished product.
•	19 June 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.