



Post Authorisation Assessments

Orniflox 25 mg/ml Concentrate for Oral Solution for Pet Rabbits, Rodents, Ornamental Birds and Reptiles Vm 43564/4001

•	01 July 2024	Addition or replacement of a measuring or administration device which is not an integrated part of the primary packaging. (NI)
•	11 December 2023	Submission of an updated certificate of suitability. (NI)
•	21 July 2023	Submission of an updated certificate of suitability of active substance.
•	21 December 2020	Renewal – UK as CMS.
•	12 December 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	30 October 2018	Change in RMS from UK to NL.
•	02 June 2017	Deletion of a non-significant specification parameter of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Increase in the shelf-life of the finished product after dilution to 12 hours. Change in the SPC, labelling or package leaflet due to new data.
•	04 August 2016	Changes to the labelling, which are not connected with the SPC.