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Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021, please refer to the <u>EMA</u> website.

Meloxidyl 5 mg/ml Solution for Injection for Dogs and Cats

Vm 15052/5014

•	23 November 2022	Approval of mock ups.
•	14 October 2022	Change in the address of the MAH from Unit 3 Anglo Office Park, White Lion Road Amersham, Buckinghamshire HP7 9FB to Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH, United Kingdom.
•	03 August 2022	Change in batch size up to 10-fold compared to originally approved size.
•	22 April 2021	Deletion of a non-significant in-process test applied during the manufacture of the finished product. Addition of new tests and limits applied during the manufacture of the finished product. Minor change to an approved test procedure for an excipient. Minor changes to an approved test procedure of the finished product. Deletion of a non-significant specification parameter of the immediate packaging of the finished product. Change to comply with Ph. Eur. Deletion of a non-significant in-process test applied during the manufacture of the finished product. Deletion of a non-significant in-process test applied during the manufacture of the finished product. Deletion of a non-significant in-process test applied during the manufacture of the finished product.
•	25 March 2021	Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.