



Post Authorisation Assessments

Norbrook Meloxicam 1.5mg/ml Oral Suspension for Dogs

Vm 02000/4396

•	16 April 2024	Changes to the product literature to bring it into line with the reference product.
•	02 June 2023	Change in dimensions of the container closure system of a non-sterile finished product.
•	01 June 2023	Removal of Local Representative MiGroup, CVS House, Owen Road, Diss, Norfolk, IP22 4ER, United Kingdom.
•	14 March 2023	Editorial changes to part 2 of the dossier.
•	08 March 2023	New certificate of suitability from a new manufacturer.
•	06 December 2022	Change of name of the veterinary medicinal product range from Meloxid 0.5mg/ml Oral Suspension for Cats and Meloxid 1.5mg/ml Oral Suspension for Dogs to Norbrook Meloxicam 0.5mg/ml Oral Suspension for Cats and Norbrook Meloxicam 1.5mg/ml Oral Suspension for Dogs.
•	06 December 2022	Change of Distributor address from iGroup, CVS House Owen Road, Diss, Norfolk, IP22 4ER, United Kingdom to Norbrook Laboratories Limited, Carnbane Industrial Estate, Newry, BT35 6QQ, Co Down, Northern Ireland.
•	01 December 2022	Variation to change the shelf-life assay specification of meloxicam in the finished product.
•	04 May 2022	Deletion of a non-significant specification parameter of an excipient.
•	13 July 2021	Change in the batch size of the finished product.
•	23 March 2021	Renewal - National.
•	26 January 2021	Change in the address of the local representative.
•	17 March 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	30 July 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	22 August 2018	Changes to the labelling and package leaflet.
•	21 May 2018	Change in distributor details. From MiGroup, 12b Progress Way, Mid-Suffolk Business Park Eye, IP23 7HU, United Kingdom to MiGroup, CVS House, Owen Road, Diss, Norfolk, IP22 4ER, United Kingdom.
•	26 October 2016	Adjusted specification for finished drug product filling volume. Adjusted specification for finished drug product filling volume.

