Veterinary Medicines Directorate

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Post Authorisation Assessments

Libromide 325mg Tablets for Dogs

Vm 10434/4073

•	June 2024	Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State. Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State. Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State. Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State. Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State.
•	May 2024	Update to the supplier name for an excipient of the finished product. (GB)
•	11 May 2024	Change to comply with Ph. Eur. for active substance specification in the ASMF. (NI)
•	28 April 2024	Changes in the manufacturing process of the active substance: - Minor change to the restricted part of an Active Substance Master File.
•	28 April 2024	Change in the manufacturing process of the finished product, - Minor change in the manufacturing process.
•	23 April 2024	Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State.
•	04 January 2024	Change in shape of the container or closure (immediate packaging) of a non-sterile finished product. Addition of a primary packaging site of a non-sterile finished product. Addition of a secondary packaging site of a finished product. (GB & NI)
•	22 December 2023	Change to comply with Ph. Eur. for active substance specification in the ASMF. (GB)
•	14 September 2023	Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product.
•	07 July 2023	Replacement manufacturing site for batch testing and batch release.
•	25 March 2021	Addition of a manufacturer of the active substance or addition of a site of manufacture.
•	18 June 2019	Addition of a manufacturer responsible for batch release including batch control/testing.
•	12 February 2019	Changes to an existing pharmacovigilance system as described in the DDPS.
•	01 August 2018	Change in RMS from UK to IE.
•	30 July 2015	Renewal

•	29 July 2014	Approval of amended mock-ups.
•	19 February 2014	Change in the manufacture of the active substance.
•	21 November 2013	Change in the immediate packaging of the finished product.
•	03 May 2013	Updates to the SPC and product literature.
•	19 December 2012	Repeat Use procedure.
•	11 November 2011	New MA - MRP
•	12 October 2011	To introduce a new pharmacovigilance system.
•	13 April 2011	To change the MAH from Genitrix Limited to Dechra Limited.