

## Post Authorisation Assessments

### Libromide 325mg Tablets for Dogs Vm 50406/3020

12 May 2026	ATC vet code becomes QN03AX91.
12 May 2026	Alignment of the product information with version 9.0* of the QRD templates.
13 February 2025	Change in legal entity of MA holder from Dechra Limited, Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, BD23 2RW, United Kingdom to Dechra Regulatory B.V., Handelsweg 25, 5531 AE Bladel, The Netherlands.
11 December 2024	Deletion of a manufacturer responsible for assembly, batch control and batch release.
18 June 2024	Update to the supplier name for an excipient of the finished product.
12 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.