Veterinary Medicines Directorate

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Post Authorisation Assessments

Gleptoferron Labiana 200 mg/ml Solution for Injection

Vm 32112/4001

13 October 2026	Change in the name and the address of the distributor to Interchem (Ireland) Ltd, Unit 29, Cookstown Industrial Estate, Dublin 24, Phone 01 451 8959, E-mail:SADR@interchem.ie. (GB + NI).
30 June 2026	Deletion of an in-process test which may have a significant effect on the overall quality of the finished product. Minor change in the manufacturing process.
22 December 2025	Change in the name of the local Representative from Labiana Life Sciences SA Calle Venus 26 08228 Terrassa Barcelona Spain Tel: +34 937369700 to Interchem (Ireland) Ltd, Unit 29, Cookstown Industrial Estate, Dublin 24, Phone 01 451 8959 and or E-mail: SADR@interchem.ie.
28 October 2025	One-off alignment of the product information with version 9.0* of the QRD templates.
14 May 2025	Change in the manufacturer of a starting material used in the manufacturing process of the active substance. Change in the specification parameters and limits of the immediate packaging of the active substance. Change in the specification parameters of an active substance and a starting material used in the manufacturing process of the active substance.
19 January 2025	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI).
03 July 2024	Substantial changes in an updated version of the active substance part of the dossier. (NI)
21 November 2023	Change in the packaging material of the bulk intermediate product. (GB)
18 May 2022	Introduction of a new site of manufacture.
09 March 2022	Renewal – UK/NI as CMS.
20 February 2018	Change in the number of units in a pack within the range of the currently approved pack sizes of the finished product.