Published by
Ministry of Health, Labour and Welfare

Translated by
Pharmaceuticals and Medical Devices Agency

Revision of Precautions

Glatiramer acetate

November 5, 2020

Therapeutic category

Agents affecting metabolism, n.e.c. (not elsewhere classified)

Non-proprietary name

Glatiramer acetate

Safety measure

Precautions should be revised in the package insert.

Pharmaceuticals and Medical Devices Agency

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Revision in line with the Instructions for Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director General of Pharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions): Revised language is underlined.

Current	Revision
Important Precaution (N/A)	Important Precaution Hepatic impairment may occur. Liver function tests should be performed prior to the initiation of, and periodically during, the administration of this drug.
Adverse Reactions Clinically Significant Adverse Reactions (N/A)	Adverse Reactions Clinically Significant Adverse Reactions Hepatic impairment: Hepatic impairment accompanied by increased levels of AST and ALT, etc. may occur. If any abnormalities are observed, appropriate measures should be taken such as discontinuing administration of this drug.

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Revision in line with the Instructions for Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0608-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 8, 2017 (New instructions): Revised language is underlined.

Current	Revision
8. IMPORTANT PRECAUTIONS (N/A)	8. IMPORTANT PRECAUTIONS <u>Hepatic impairment may occur. Liver function tests should be performed prior to the initiation of, and periodically during, the administration of this drug.</u>
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions(N/A)	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions <u>Hepatic impairment</u> <u>Hepatic impairment accompanied by increased levels of AST and ALT, etc. may occur.</u>

N/A: Not Applicable, because the section is not included in the current package insert.

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