Published by
Ministry of Health, Labour and Welfare

Translated by
Pharmaceuticals and Medical Devices Agency

Revision of Precautions

Alemtuzumab

（genetical recombination）

January 21, 2020

Therapeutic category

Antineoplastics-miscellaneous

Non-proprietary name

Alemtuzumab (genetical recombination)

Safety measure

Precautions should be revised in the package insert.

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

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
Adverse Reactions Clinically Significant Adverse Reactions (N/A)	Adverse Reactions Clinically Significant Adverse Reactions Cervicocephalic arterial dissection: Cervicocephalic arterial dissection such as carotid or vertebral artery dissection may occur and cases that led to ischaemic stroke have been reported. Patients should be carefully monitored and appropriate measures should be taken such as temporal discontinuation or discontinuation of this drug if any abnormalities are observed.

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
11. Adverse Reactions 11.1 Clinically Significant Adverse Reactions(N/A)	11. Adverse Reactions 11.1 Clinically Significant Adverse Reactions Cervicocephalic arterial dissection Cervicocephalic arterial dissection such as carotid or vertebral artery dissection may occur and cases that led to ischaemic stroke have been reported.

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

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp