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Revision of Precautions

Alemtuzumab (genetical recombination)

January 26, 2021

Therapeutic category

Other antitumor agents

Non-proprietary name

Alemtuzumab (genetical recombination)

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, 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 PRECAUTIOS <u>Abnormal thyroid function may occur. Patients should be carefully monitored through thyroid function tests performed prior to, and during, administration of this drug.</u>
11. ADVERSE REACTIONS 11.1 Clinically Significant adverse Reactions Immune disorder Immune disorder may occur such as autoimmune haemolytic anaemia, autoimmune thrombocytopenia, autoimmune hepatitis, aplastic anaemia, Guillain-Barre syndrome, chronic inflammatory demyelinating polyneuritis, or post transfusion graft versus host disease, resulting in a fatal outcome reported in some cases. Administration of this drug should be discontinued if autoimmune haemolytic anaemia or autoimmune thrombocytopenia is observed.	11. ADVERSE REACTIONS 11.1 Clinically Significant adverse Reactions Immune disorder Immune disorder may occur such as autoimmune haemolytic anaemia, autoimmune thrombocytopenia, autoimmune hepatitis, aplastic anaemia, Guillain-Barre syndrome, chronic inflammatory demyelinating polyneuritis, post transfusion graft versus host disease<u>, hypothyroidism, or hyperthyroidism</u>, resulting in a fatal outcome reported in some cases. Administration of this drug should be discontinued if autoimmune haemolytic anaemia or autoimmune thrombocytopenia is observed.

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

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