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Translated by
Pharmaceuticals and Medical Devices Agency



This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Revision of Precautions

Belimumab (genetical recombination)

October 29, 2019

Therapeutic category

Miscellaneous metabolism agents-miscellaneous

Non-proprietary name

Belimumab (genetical recombination)

Safety measure

Precautions should be revised in the package insert.

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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
<p>Important Precautions (N/A)</p> <p>Adverse Reactions Clinically Significant Adverse Reactions (N/A)</p>	<p>Important Precautions</p> <p><u>Depression, suicidal ideation, or suicide attempt may occur.</u> <u>Patients and their families or other caregivers should be fully informed of the risk of these events and instructed to contact the attending physician immediately if any changes occur in the psychiatric status of patients such as insomnia or anxiety.</u></p> <p>Adverse Reactions Clinically Significant Adverse Reactions</p> <p><u>Depression, suicidal ideation, and suicide attempt:</u> <u>Depression, suicidal ideation, and suicide attempt may occur.</u> <u>Patients should be closely monitored and appropriate measures such as discontinuing this drug should be taken if any abnormalities are observed.</u></p>

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

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