

This document is an English-translated version of an attachment of a notification for Revision of PRECAUTIONS issued by the Ministry of Health, Labour and Welfare.

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

Adalimumab (genetical recombination)

Adalimumab (genetical recombination)

[adalimumab follow-on biologics 1]

Adalimumab (genetical recombination)

[adalimumab follow-on biologics 2]

Adalimumab (genetical recombination)

[adalimumab follow-on biologics 3]

Adalimumab (genetical recombination)

[adalimumab follow-on biologics 4]

September 9, 2025

Therapeutic category

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

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Non-proprietary name

Adalimumab (genetical recombination)

Adalimumab (genetical recombination) [adalimumab follow-on biologics 1]

Adalimumab (genetical recombination) [adalimumab follow-on biologics 2]

Adalimumab (genetical recombination) [adalimumab follow-on biologics 3]

Adalimumab (genetical recombination) [adalimumab follow-on biologics 4]

Safety measure

PRECAUTIONS should be revised.

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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 <u>Autoimmune hepatitis</u>

N/A: Not Applicable. No corresponding language is included in the current PRECAUTIONS.