

*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

Infliximab (genetical recombination)

Infliximab (genetical recombination)

[Infliximab biosimilar 1]

Infliximab (genetical recombination)

[Infliximab biosimilar 2]

Infliximab (genetical recombination)

[Infliximab biosimilar 3]

Etanercept (genetical recombination)

Etanercept (genetical recombination)

[Etanercept biosimilar 1]

Etanercept (genetical recombination)

[etanercept biosimilar 2]

April 21, 2026

Therapeutic category

Other agents affecting digestive organs

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

Non-proprietary name

Infliximab (genetical recombination) and biosimilars

Etanercept (genetical recombination) and biosimilars

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.