

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.

Attachment 6
July 14, 2026

【Therapeutic category】 399 Agents affecting metabolism, n.e.c. (not elsewhere classified)
【Non-proprietary name】 Guselkumab (genetical recombination)
【Safety measure】 PRECAUTIONS should be revised.

A revised description is underlined.

Current	Revision
8. IMPORTANT PRECAUTIONS (N/A)	8. IMPORTANT PRECAUTIONS <u>Hepatic impairment including autoimmune hepatitis may occur. Patients should be carefully monitored for their condition through such methods as periodic liver function tests.</u>
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (N/A)	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions <u>Hepatic impairment</u> <u>Hepatic impairment including autoimmune hepatitis may occur.</u>

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

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.