

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

Vedolizumab (genetical recombination)

December 17, 2024

Therapeutic category

Other agents affecting digestive organs

Non-proprietary name

Vedolizumab (genetical recombination)

Safety measure

PRECAUTIONS should be revised.

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>Interstitial lung disease</u> <u>Interstitial lung disease (interstitial pneumonia, eosinophilic pneumonia, etc.) has been reported. If cough, dyspnoea, pyrexia, abnormal chest sound (crepitations), etc. are observed, examinations such as chest X-ray, chest CT scan, and serum marker test should be promptly performed. If interstitial lung disease is suspected, administration of this drug should be discontinued, and appropriate measures such as administration of corticosteroids should be taken.</u>

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