

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

Ethyl icosapentate (300 mg/600 mg/900 mg)

November 13, 2024

Therapeutic category

Agents for hyperlipidemias

Other agents relating to blood and body fluids

Non-proprietary name

Ethyl icosapentate (300 mg/600 mg/900 mg)

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>Atrial fibrillation, atrial flutter</u> <u>It was reported that an increased risk of atrial fibrillation or atrial flutter requiring hospitalization was observed in the overseas clinical trial of ethyl icosapentate (4g/day^{Note})). In addition, it was reported that an increased risk of atrial fibrillation was observed in Japanese and overseas clinical studies of omega-3-acid ethyl esters including those of ethyl icosapentate.</u> <u>Note) The approved maximum daily dose of ethyl icosapentate is 2,700 mg for hyperlipidaemia.</u>

[References] Bhatt, D. L. et al.: N. Engl. J. Med. 2019; 380(1): 11-22

Miyauchi, K. et al.: Circulation 2024; 150(6): 425-434

Nicholls, S. J. et al.: JAMA. 2020; 324(22): 2268-2280

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