

*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

## Omega-3-acid ethyl esters

November 13, 2024

### **Therapeutic category**

Agents for hyperlipidemias

### **Non-proprietary name**

Omega-3-acid ethyl esters

### **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). 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>

[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.