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 (OTC drug)

November 13, 2024

Therapeutic category

Drugs for improving serum high cholesterol

Non-proprietary name Ethyl icosapentate (OTC drug)

Safety measure PRECAUTIONS should be revised.

Revised language is underlined.

Current	Revision	
Consultation	Consultation	
If the following symptoms are observed after taking this drug, they may	If the following symptoms are observed after taking this drug, they may	
be adverse reactions. In such cases, the use of this drug should be	be adverse reactions. In such cases, the use of this drug should be	
immediately discontinued, and a physician or pharmacist should be	immediately discontinued, and a physician or pharmacist should be	
consulted, presenting them with this document.	consulted, presenting them with this document.	
The following serious symptoms may occur rarely. In such cases,	The following serious symptoms may occur rarely. In such cases,	
medical attention should be sought immediately.	medical attention should be sought immediately.	
(N/A)	Name of symptoms	Symptoms
	Atrial fibrillation, atrial	Symptoms such as palpitations, chest
	<u>flutter</u>	discomfort, dizziness, skipped heartbeats
		may occur.

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