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.