Summary of Investigation Results

Ethyl icosapentate
Omega-3-acid ethyl esters

November 13, 2024

Non-proprietary name

a. Ethyl icosapentate

b. Omega-3-acid ethyl esters

Brand name (marketing authorization holder)

a. Epadel Capsules 300, Epadel S Capsules 300, 600, 900, Epadel EM Capsules 2 g (Mochida Pharmaceutical Co., Ltd.), and the others

b. Lotriga Granular Capsules 2 g (Takeda Pharmaceutical Company Limited) and the others

Japanese market launch

a. Capsules 300: June 1990
S300, S600: January 1999
S900: July 2004
EM Capsules 2g: September 2022

b. January 2013

Indications

a. <Capsules 300, S300, S600, S900>
•Improvement of ulcer, pain, and cold feeling associated with arteriosclerosis obliterans
•Hyperlipidaemia
<EM Capsules 2g>
Hyperlipidaemia

b. Hyperlipidaemia

Summary of revisions

"Atrial fibrillation, atrial flutter" should be added to the 11.1 Clinically Significant Adverse Reactions in 11. ADVERSE REACTIONS.

Investigation results and background of the revision

Published literature related to atrial fibrillation and atrial flutter after administration of ethyl icosapentate or omega-3-acid ethyl esters was evaluated. There have been reports suggesting an increased risk of atrial fibrillation or atrial flutter*. As a result of consultation with expert advisors, the MHLW/PMDA concluded that revision of PRECAUTIONS was appropriate.

*: 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

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the "Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency" (PMDA Administrative Rule No. 20-8, dated December 25, 2008).