



# Summary of Investigation Results

## Ethyl icosapentate (OTC drug)

November 13, 2024

### Non-proprietary name

Ethyl icosapentate (OTC drug)

### Brand name (marketing authorization holder)

Epadel T (Mochida Pharmaceutical Co., Ltd.)

### Japanese market launch

April 2013

### Indications

Improvement of borderline<sup>Note)</sup> levels of triglyceride suggested by a medical examination, etc.

Note) "Borderline" refers to triglyceride levels that are slightly higher than normal levels (150 mg/dL or higher and less than 300 mg/dL) in the medical examinations, etc.

### Summary of revisions

"Atrial fibrillation, atrial flutter" should be added to the Consultation section.

### Investigation results and background of the revision

As a result of consultation with expert advisors, since the PRECAUTIONS of the prescription drugs will be revised, the MHLW/PMDA concluded that a similar revision of PRECAUTIONS was necessary for the OTC drug.

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).