This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Summary of Investigation Results
Pemafibrate

October 12, 2022

Non-proprietary name

Pemafibrate

Brand name (Marketing authorization holder)

Parmodia Tab. 0.1 mg (Kowa Company, Ltd.)

Indications

Hyperlipidemia (including familial)

Summary of revisions

1. Contraindication in “patients with renal impairment whose serum creatinine value is greater than or equal to 2.5 mg/dL or creatinine clearance is less than 40 mL/min” should be deleted and the language concerning Precautions concerning Dosage and Administration, Careful Administration and Important Precautions sections should be revised.
2. The results of the clinical study (PALT02 Study) in patients with severe renal impairment should be added to the PHARMACOKINETICS section.

Investigation results and background of the revision

The results of PALT02 Study and the occurrence of adverse events related to rhabdomyolysis reported post-marketing were evaluated. As a result of this, MHLW/PMDA in consultation with expert advisors concluded that revision of Precautions was necessary.

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).

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