



Summary of Investigation Results

Pemafibrate

August 27, 2024

Non-proprietary name

Pemafibrate

Brand name (marketing authorization holder)

Parmodia Tablets 0.1 mg, Parmodia XR Tablets 0.2 mg, 0.4 mg (Kowa Company, Ltd.)

Japanese market launch

June 2018 (Tablets)

November 2023 (XR Tablets)

Indications

Hyperlipidaemia (including familial hyperlipidaemia)

Summary of revisions

“Hepatic impairment, jaundice” should be added to the 11.1 Clinically Significant Adverse Reactions section in 11. ADVERSE REACTIONS.

Investigation results and background of the revision

Cases involving hepatic impairment were evaluated. Cases for which a causal relationship between pemafibrate and hepatic impairment was reasonably possible, including those accompanied by jaundice, have been reported. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of PRECAUTIONS, the MHLW/PMDA concluded that revision of PRECAUTIONS to add hepatic impairment and jaundice was necessary.

Reference: Number of cases*† and patient mortalities involving hepatic impairment



reported in Japan

A total of 25 cases have been reported to date. (A causal relationship between the drug and event was reasonably possible for 9 cases, including 3 cases accompanied by jaundice.)

No patient mortalities have been reported to date.

* Cases collected in the PMDA's database for adverse drug reactions, etc. reports

† Among the cases retrieved by MedDRA ver.27.0 SMQ “Drug related hepatic disorders-comprehensive search,” those falling under grade 3 or higher by Common Terminology Criteria for Adverse Events (CTCAE) version 5.0 were retrieved.

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).