



Summary of investigation results

Lenvatinib mesilate

January 11, 2018

Non-proprietary name

Lenvatinib mesilate

Brand name (Marketing authorization holder)

Lenvima Capsules 4 mg and 10 mg (Eisai Co., Ltd.)

Indications

Unresectable thyroid cancer

Summary of revision

“Acute cholecystitis” should be newly added in the Clinically Significant Adverse Reactions section.

Background of the revision and investigation results

The company core data sheet (CCDS) has been updated and cases of acute cholecystitis have been reported in patients treated with lenvatinib mesilate in Japan and overseas. Following investigation results based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan

A total of 11 cases associated with acute cholecystitis have been reported (including 4 cases for which a causal relationship to the product could not be ruled out). Two fatalities have been reported (including 0 cases for which a causal relationship to the product could not be ruled out).