



Summary of Investigation Results

Lenvatinib mesilate

October 23, 2018

Non-proprietary name

Lenvatinib mesilate

Branded name (Marketing authorization holder)

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

Indications

Unresectable thyroid cancer, unresectable hepatocellular carcinoma

Summary of revisions

- “Patient with lung metastasis” should be added to the Careful Administration section.
- “Pneumothorax” should be added to the language concerning gastrointestinal perforation and fistula formation in the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of pneumothorax have been reported in patients treated with lenvatinib mesilate in Japan. MHLW/PMDA concluded that revision of the package insert was necessary based on the results of their investigation of the currently available evidence and in consultation with expert advisors.

Number of adverse reactions and patient mortalities reported in Japan during the previous 3 fiscal years

A total of 11 cases involving pneumothorax have been reported to date (including 10 cases for which a causal relationship with the product could not be ruled out.)

One instance of patient mortality has been reported to date (a causal relationship with the product could not be established in this case.)

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