



# Summary of investigation results

## Lenvatinib mesilate

November 24, 2015

### Non-proprietary name

Lenvatinib mesilate

### Brand name (Marketing authorization holder)

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

### Indications

Radically unresectable thyroid cancer

### Summary of revision

1. “Patients with tumour invasion in the carotid arteries, veins, etc.” should be newly added in the Careful Administration section.
2. Precautions regarding “carotid artery exposure, carotid artery haemorrhage, and tumour haemorrhage associated with tumour shrinkage or necrosis” should be newly added in the Important Precautions section.
3. Precautions regarding “carotid artery haemorrhage and tumour haemorrhage associated with tumour shrinkage or necrosis” should be added to the “Haemorrhage” subsection in the Clinically significant adverse reaction section.

### Background of the revision and investigation results

Cases of carotid artery exposure, carotid artery haemorrhage and tumour haemorrhage have been reported in patients treated with lenvatinib mesilate in Japan. There were reports of massive bleeding cases. Patients with tumour invasion in the carotid artery, jugular vein, etc. results in accumulation of cases of carotid artery haemorrhage and tumour haemorrhage. In addition, there are many cases of tumour invasion in anaplastic thyroid cancer patients. Therefore, following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

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

A total of 14 cases associated with carotid artery exposure, carotid artery haemorrhage and tumour haemorrhage have been reported (including 5 cases for which a causal relationship to the product could not be ruled out). Of the 14 cases, 6 fatal cases have been reported (a causal relationship between the product and the fatal outcome could not be established for these patients).