



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

Revision of Precautions

Lenvatinib mesilate

January 11, 2018

Non-proprietary name

Lenvatinib mesilate

Safety measure

Precautions should be revised in the package insert.

In the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section, the following text should be added (underlined parts are revised):

Acute cholecystitis:

Acute cholecystitis, including acalculous cholecystitis, may occur, and cases that led to gallbladder perforation have been reported. Patients should be monitored carefully, and if abnormalities are observed, appropriate measures should be taken such as drug suspension.