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*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

## Sunitinib malate

September 18, 2018

### **Non-proprietary name**

Sunitinib malate

### **Safety measure**

Precautions should be revised in the package insert.

The following language should be added to the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section (revised language is underlined):

Acute cholecystitis:

Acute cholecystitis, including acalculous cholecystitis, may occur. Patients should be carefully monitored, and if any abnormalities are observed, appropriate measures such as suspension of administration should be taken.