



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

Palbociclib

February 12, 2019

Non-proprietary name

Palbociclib

Safety measure

Precautions should be revised in the package insert.

The following language should be added to the Important Precautions section (revised language is underlined):

Interstitial lung disease may occur. When using this drug, patients should be carefully monitored for initial symptoms (such as dyspnoea, cough, and pyrexia) and by performing a chest X-ray, etc. A chest CT scan or serum marker test, etc. should be performed as necessary.

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

Interstitial lung disease:

Interstitial lung disease may occur. Patients should be carefully monitored. If any abnormalities are observed, appropriate measures such as discontinuing administration of this drug should be taken.