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Translated by
Pharmaceuticals and Medical Devices Agency



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

July 9, 2019

Therapeutic category

Antineoplastics-miscellaneous

Non-proprietary name

Palbociclib

Safety measure

Precautions should be revised in the package insert.

Pharmaceuticals and Medical Devices Agency

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Revision in line with the Instructions for Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director General of Pharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions): Revised language is underlined.

Current	Revision
<p>Warnings (N/A)</p>	<p>Warnings <u>Cases of interstitial lung disease resulting in mortality have been reported. Patients should be carefully monitored for initial symptoms (such as dyspnoea, cough, and pyrexia) and by performing a chest X-ray, etc. If any abnormalities are observed, administration of this drug should be discontinued and a chest CT scan or serum marker test, etc. should be performed as necessary and appropriate measures should be taken.</u></p>
<p>Careful Administration (N/A)</p>	<p>Careful Administration <u>Patients with interstitial lung disease or a history of the disease (interstitial lung disease may exacerbate.)</u></p>
<p>Important Precaution Interstitial lung disease may occur. When using this drug, patients should be carefully monitored for initial symptoms (such as dyspnoea, cough, and pyrexia) and <u>by performing a chest X-ray, etc. A chest CT scan or serum marker test, etc. should be performed as necessary.</u></p>	<p>Important Precaution 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. <u>Patients or their families should be adequately informed of adverse reactions associated with this drug and instructed to immediately contact medical institutions when they experience any initial symptoms of the disease.</u></p>

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Adverse Reactions

Clinically Significant Adverse Reactions

Interstitial lung disease:

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

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Interstitial lung disease:

Interstitial lung disease may occur. Patients should be carefully monitored. If any abnormalities are observed, this drug should be discontinued and a chest CT scan or serum marker test, etc. should be performed as necessary, and appropriate measures should be taken.

N/A: Not Applicable, because the section is not included in the current package insert.

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