



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 Vemurafenib

February 14, 2017

Non-proprietary name

Vemurafenib

Safety measure

Precautions should be revised in the package insert.

In the Important Precautions section, the following text should be added (underlined parts are revised):

Acute kidney injury may occur. Renal function tests should be performed before the start of, and periodically during, treatment.

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

Acute kidney injury: Acute kidney injury may occur. Patients should be carefully monitored.

If any abnormalities are observed, appropriate measures such as dose reduction, drug suspension, or discontinuation of administration should be adopted.