



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

Crizotinib

June 2, 2015

Non-proprietary name

crizotinib

Safety measure

Precautions should be revised in the package insert.

In the Clinically significant adverse reactions subsection of the Adverse reactions section, the following texts should be added (underlined parts are revised):

Cardiac failure:

Cardiac failure may occur. Patients should be carefully monitored. If the fluid retention (pulmonary oedema, pleural effusion, pericardial effusion, etc.), rapid increased weight, cardiac failure symptoms (shortness of breath, dyspnoea, oedema, etc.) are observed, appropriate measures such as drug suspension, dose reduction, or discontinuation of administration, should be adopted.