



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 Afatinib maleate

September 13, 2016

Non-proprietary name

Afatinib maleate

Safety measure

Precautions should be revised in the package insert.

In the Clinically significant adverse reaction subsection regarding oculomucocutaneous syndrome of the Adverse reaction section, the following text should be revised (underlined parts are revised):

Toxic epidermal necrolysis (TEN), oculomucocutaneous syndrome (Stevens–Johnson syndrome), and erythema multiforme:

Serious bullous or exfoliative skin disorders such as toxic epidermal necrolysis, oculomucocutaneous syndrome, and erythema multiforme may occur. Patients should be carefully monitored. If any abnormalities are observed, appropriate measures such as discontinuation of administration should be adopted.