



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 Nilotinib hydrochloride hydrate

August 4, 2016

Non-proprietary name

Nilotinib hydrochloride hydrate

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):

Reactivation of hepatitis B virus may occur among hepatitis B virus carriers or patients who have a history of being infected (i.e. HBs antigen negative and HBc antibody or HBs antibody positive) following administration of Bcr-Abl tyrosine kinase inhibitors. The presence or absence of hepatitis B virus infection should be confirmed prior to administering this drug and appropriate measures should be adopted before the administration of this drug. After beginning the administration of this drug, attention should be paid to the occurrence of signs or symptoms related to reactivation of the hepatitis B virus through continuous hepatic function tests, monitoring of hepatitis virus markers, etc.

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

Infections: Infections such as pneumonia and sepsis may occur. Reactivation of hepatitis B virus may also occur. Patients should be carefully monitored through periodical blood test, etc. If any abnormalities are observed, appropriate measures such as discontinuation of administration should be adopted.