



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

Dolutegravir sodium

September 18, 2018

Non-proprietary name

Dolutegravir sodium

Safety measure

Precautions should be revised in the package insert.

The language concerning initial or continuous elevation in transaminase levels in the Important Precautions section should be revised as follows (revised language is underlined):

Hepatic impairment and jaundice may occur. Patients should be carefully monitored through methods such as periodic liver function tests. In clinical studies, the frequency of cases of initial or continuous elevation in transaminase levels was higher among patients with hepatitis B and C virus co-infection compared with patients without co-infection.

The following language should be added to the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section (revised language is underlined):

Hepatic impairment, jaundice:

Hepatic impairment accompanied with elevation in AST, ALT, or bilirubin levels, and jaundice may occur. If these or any other abnormalities are observed, appropriate measures such as discontinuing administration should be taken.