



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 Asunaprevir, Daclatasvir hydrochloride

October 20, 2015

Non-proprietary name

- a. Asunaprevir
- b. Daclatasvir hydrochloride

Safety measure

Precautions should be revised in the package insert.

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

Interstitial pneumonia:

Interstitial pneumonia may occur. If cough, dyspnoea, pyrexia, abnormal chest sound (crepitations), etc. are observed, examinations including chest X-ray, chest CT scan, or serum marker test should be performed. If interstitial pneumonia is suspected, administration of this drug should be discontinued and appropriate measures should be adopted.