



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

September 15, 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):

Thrombocytopenia:

Thrombocytopenia may occur. Patients should be carefully monitored through periodic blood tests, etc. If any abnormalities are observed, appropriate measures such as discontinuation of administration should be adopted.