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*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

## Simeprevir sodium

July 8, 2014

### Non-proprietary Name

Simeprevir sodium

### Safety measure

Precautions should be revised in the package inserts.

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

#### Sepsis:

Susceptibility to infection may be increased, resulting in serious infection leading to sepsis.  
Patients should be carefully monitored through periodic blood tests, etc. If any abnormalities are observed, administration of this drug should be discontinued, and appropriate measures should be taken.

#### Cerebral haemorrhage:

Cerebral haemorrhage may occur. Patients should be carefully monitored. If any abnormalities are observed, administration of this drug should be discontinued, and appropriate measures should be taken.