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.