Revision of Precautions
simeprevir sodium

January 9, 2015

Non-proprietary Name
simeprevir sodium

Safety measure
Precautions should be revised in the package insert.

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

Leukopenia, neutropenia:
Leukopenia and/or neutropenia may occur. Patients should be carefully monitored through periodic blood tests, etc. If the abnormality is severe, discontinuation of administration should be considered and appropriate measures should be taken.