



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

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.