



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

Hepatitis C Direct Acting Antivirals

Asunaprevir, Simeprevir Sodium, Telaprevir, Vaniprevir,

May 18, 2016

Non-proprietary name

- a. Asunaprevir
- b. Simeprevir Sodium
- c. Telaprevir
- d. Vaniprevir

Safety measure

Precautions should be revised in the package insert.

In the Careful Administration section, the following text should be added (underlined parts are revised):

Patients currently infected with hepatitis B virus or patients with a history of hepatitis B virus infection.

In the Important Precautions section, the following text should be added (underlined parts are revised):

Reactivation of hepatitis B virus has been reported in association with decrease in hepatitis C viral load after initiating treatment with hepatitis C direct acting antivirals among patients who are infected with the hepatitis B virus or patients who have a history of being infected (i.e. HBs antigen negative and HBc antibody or HBs antibody positive). The presence or absence of hepatitis B virus infection should be

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confirmed prior to administrating this drug. If this drug is administered to patients who are infected with the hepatitis B virus or to patients who have a history of infection, attention should be paid to the occurrence of signs or symptoms related to reactivation of hepatitis B virus by monitoring results of hepatitis B virus markers such as HBV DNA load.