



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

Ombitasvir Hydrate/Paritaprevir Hydrate/Ritonavir, Sofosbuvir, Daclatasvir Hydrochloride

Ledipasvir Acetate/Sofosbuvir,

May 18, 2016

Non-proprietary name

- a. Ombitasvir Hydrate/Paritaprevir Hydrate/Ritonavir
- b. Sofosbuvir
- c. Daclatasvir Hydrochloride
- d. Ledipasvir Acetate/Sofosbuvir

Safety measure

Precautions should be revised in the package insert.

The Careful Administration section should be newly added in the package insert. In this new 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.

Pharmaceuticals and Medical Devices Agency

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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 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.