



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

Ombitasvir hydrate/Paritaprevir hydrate/Ritonavir

Non-proprietary name

Ombitasvir hydrate/Paritaprevir hydrate/Ritonavir

Safety measure

Precautions should be revised in the package insert.

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

Prior to the start of administration of this drug and periodically during treatment, renal function tests (serum creatinine, BUN, etc.) should be performed. Renal function may suddenly deteriorate in particular patients with decreased renal function and patients concomitantly administered calcium channel blockers. Therefore, these patients should be carefully monitored. If any abnormalities are observed, appropriate measures such as discontinuation of administration should be adopted.

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

Acute renal failure

Acute renal failure may occur. Patients should be carefully monitored through periodic renal function tests, etc. If any abnormalities are observed, appropriate measures such as discontinuation of administration should be adopted.