



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

Glecaprevir hydrate/pibrentasvir

February 12, 2019

Non-proprietary name

Glecaprevir hydrate/pibrentasvir

Safety measure

Precautions should be revised in the package insert.

The following language should be added to the Important Precautions section (revised language is underlined):

Hepatic impairment and jaundice may occur. Patients should be carefully monitored through methods such as periodic liver function tests.

A Clinically Significant Adverse Reactions subsection should be newly added to the Adverse Reaction section and the following language should be included (revised language is underlined):

Hepatic impairment, jaundice:

Hepatic impairment accompanied with elevation in AST, ALT, or bilirubin levels, and jaundice may occur. If these or any other abnormalities are observed, appropriate measures such as discontinuing administration should be taken.