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# Revision of Precautions

## Asunaprevir, Daclatasvir hydrochloride

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### Non-proprietary name

a. Asunaprevir

b. Daclatasvir hydrochloride

### Safety measure

Precautions should be revised in the package insert.

Information on hepatic function disorder in the Important precautions section should be revised as follows (underlined parts are revised):

> Hepatic function disorder and/or decreased hepatic residual function may occur and may result in hepatic failure. Hepatic function should be assessed at least every 2 weeks until 12 weeks after the start of administration and every 4 weeks after 12 weeks. If deterioration in hepatic function is observed, hepatic function should be assessed more frequently, and appropriate measures such as discontinuation of administration should be adopted. In addition, regardless of increased hepatic enzyme levels, hepatic failure associated with jaundice, ascites, hepatic encephalopathy, etc. may occur. 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 reactions subsection of the Adverse reactions section, the following text should be revised (underlined parts are revised):

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Hepatic function disorder and hepatic failure:

Increased ALT [GPT] level, increased AST [GOT] level, increased blood bilirubin level, prolonged prothrombin time, decreased albumin level, etc. may occur and may result in hepatic failure associated with jaundice, ascites, hepatic encephalopathy, etc. Hepatic function should be assessed at least every 2 weeks until 12 weeks after the start of administration and every 4 weeks after 12 weeks. If deterioration in hepatic function is observed, hepatic function should be assessed more frequently, and appropriate measures such as discontinuation of administration should be adopted. If ALT (GPT) increases ≥10 times the upper limit of normal, administration should be discontinued immediately and should not be re-administered.

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