



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

Asunaprevir

Daclatasvir hydrochloride

Daclatasvir

hydrochloride/asunaprevir/beclabuvir

hydrochloride

January 10, 2019

Non-proprietary name

Asunaprevir

Daclatasvir hydrochloride

Daclatasvir hydrochloride/asunaprevir/beclabuvir hydrochloride

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):

Renal impairment such as acute kidney injury may occur. Patients should be carefully monitored through methods such as periodic renal function tests.

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The following language should be added to the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section (revised language is underlined):

Renal impairment:

Renal impairment such as acute kidney injury may occur. If any abnormalities are observed, appropriate measures such as discontinuing administration should be taken.

Pharmaceuticals and Medical Devices Agency

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