



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

Ledipasvir acetate / Sofosbuvir

Non-proprietary name

Ledipasvir acetate / Sofosbuvir

Safety measure

Precautions should be revised in the package insert.

The Clinically significant adverse reaction subsection of the Adverse reactions section should be newly added in the package insert. In this new Clinically significant adverse reaction subsection, the following text should be added (underlined parts are revised):

Hypertension

Hypertension may occur. Cases of systolic blood pressure greater than or equal to 180 mmHg or diastolic blood pressure greater than or equal to 110 mmHg have been reported with this drug. Patients should be carefully monitored through changes in blood pressure, etc., during administration of this drug. If any abnormalities are observed, appropriate measures such as discontinuation of administration drug should be adopted.

Cerebrovascular disorder

Cerebrovascular disorders, such as cerebral infarction and cerebral hemorrhage, may occur. Patients should be carefully monitored. If any abnormalities are observed, appropriate measures such as discontinuation of administration should be adopted.