



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

Ribavirin

Non-proprietary name

Ribavirin (which has the indication for concomitant use with sofosbuvir)

Safety measure

Precautions should be revised in the package insert.

In the Clinically significant adverse reaction subsection regarding <Concomitant use with sofosbuvir> of the Adverse reaction section, 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 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.