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Pharmaceuticals and Medical Devices Agency

Revision of Precautions

Asunaprevir

Glecaprevir hydrate/pibrentasvir

Sofosbuvir

Daclatasvir hydrochloride

Ledipasvir acetonate/sofosbuvir

February 25, 2020

Therapeutic category

Antivirals

Pharmaceuticals and Medical Devices Agency

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Non-proprietary name

Asunaprevir

Glecaprevir hydrate/pibrentasvir

Sofosbuvir

Daclatasvir hydrochloride

Ledipasvir acetonate/sofosbuvir

Safety measure

Precautions should be revised in the package insert.

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Revision in line with the Instructions for Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director General of Pharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions): Revised language is underlined.

Current	Revision
Important Precautions (N/A)	Important Precautions Cases where a dose increase of warfarin or tacrolimus or a reduction of insulin or other antidiabetic agents due to hypoglycemia were required following initiation of a direct-acting antiviral(s) for hepatitis C have been reported. Dose adjustment for concomitant drugs may be required in association with anti-viral treatment with this drug. In particular, if patients on warfarin, tacrolimus or other drugs with a narrow therapeutic window that are metabolized by the liver, or on antidiabetic agents are initiated on this drug, their prescribing physicians of such drugs in principle should be informed of the initiation and the patients should be carefully monitored for their conditions through methods such as frequent monitoring of PT-INR, blood drug concentration, or blood sugar levels.

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Revision in line with the Instructions for Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0608-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 8, 2017 (New instructions): Revised language is underlined.

Current	Revision
8. IMPORTANT PRECAUTIONS (N/A)	8. IMPORTANT PRECAUTIONS Cases where a dose increase of warfarin or tacrolimus or a reduction of insulin or other antidiabetic agents due to hypoglycemia were required following initiation of a direct-acting antiviral(s) for hepatitis C have been reported. Dose adjustment for concomitant drugs may be required in association with anti-viral treatment with this drug. In particular, if patients on warfarin, tacrolimus or other drugs with a narrow therapeutic window that are metabolized by the liver, or on antidiabetic agents are initiated on this drug, their prescribing physicians of such drugs in principle should be informed of the initiation and the patients should be carefully monitored for their conditions through methods such as frequent monitoring of PT-INR, blood drug concentration, or blood sugar levels.

N/A: Not Applicable, because the section is not included in the current package insert.

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