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Translated by
Pharmaceuticals and Medical Devices Agency



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

Sofosbuvir/velpatasvir

February 25, 2020

Therapeutic category

Aitivirals

Non-proprietary name

Sofosbuvir/velpatasvir

Safety measure

Precautions should be revised in the package insert.

Pharmaceuticals and Medical Devices Agency

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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
<p>Important Precautions (N/A)</p>	<p>Important Precautions <u>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.</u></p>

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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
<p>8. IMPORTANT PRECAUTIONS (common to all indications) (N/A)</p>	<p>8. IMPORTANT PRECAUTIONS (common to all indications) <u>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.</u></p>

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

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