

This document is an English-translated version of an attachment of a notification for Revision of PRECAUTIONS issued by the Ministry of Health, Labour and Welfare.

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

Ensitrelvir fumaric acid

February 10, 2026

Therapeutic category

Anti-virus agents

Non-proprietary name

Ensitrelvir fumaric acid

Safety measure

PRECAUTIONS should be revised.

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Revised language is underlined.

Current	Revision
<p>2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.)</p> <p>Patients receiving the following drugs: Pimozide, quinidine sulfate hydrate, bepridil hydrochloride hydrate, ticagrelor, eplerenone, ergotamine tartrate/anhydrous caffeine/isopropylantipyrine, ergometrine maleate, methylergometrine maleate, dihydroergotamine mesilate, simvastatin, triazolam, anamorelin hydrochloride, ivabradine hydrochloride, venetoclax [during its dose escalation phase for relapsed or refractory chronic lymphocytic leukemia (including small lymphocytic lymphoma)], ibrutinib, blonanserin, lurasidone hydrochloride, azelnidipine, azelnidipine/olmesartan medoxomil, suvorexant, daridorexant hydrochloride, vornorexant hydrate, tadalafil (Adcirca), macitentan/tadalafil, vardenafil hydrochloride hydrate, lomitapide mesilate, rifabutin, finerenone, voclosporin, lonafarnib, mavacamten, rivaroxaban, <u>riociguat</u>, apalutamide, carbamazepine, enzalutamide, mitotane, phenytoin, fosphenytoin sodium hydrate, rifampicin, or food containing St. John's Wort</p> <p>10. INTERACTIONS</p> <p>10.1 Contraindications for Co-administration (Do not co-administer with the following.)</p>	<p>2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.)</p> <p>Patients receiving the following drugs: Pimozide, quinidine sulfate hydrate, bepridil hydrochloride hydrate, ticagrelor, eplerenone, ergotamine tartrate/anhydrous caffeine/isopropylantipyrine, ergometrine maleate, methylergometrine maleate, dihydroergotamine mesilate, simvastatin, triazolam, anamorelin hydrochloride, ivabradine hydrochloride, venetoclax [during its dose escalation phase for relapsed or refractory chronic lymphocytic leukemia (including small lymphocytic lymphoma)], ibrutinib, blonanserin, lurasidone hydrochloride, azelnidipine, azelnidipine/olmesartan medoxomil, suvorexant, daridorexant hydrochloride, vornorexant hydrate, tadalafil (Adcirca), macitentan/tadalafil, vardenafil hydrochloride hydrate, lomitapide mesilate, rifabutin, finerenone, voclosporin, lonafarnib, mavacamten, rivaroxaban, <u>apalutamide</u>, carbamazepine, enzalutamide, mitotane, phenytoin, fosphenytoin sodium hydrate, rifampicin, or food containing St. John's Wort</p> <p>10. INTERACTIONS</p> <p>10.1 Contraindications for Co-administration (Do not co-administer with the following.)</p>

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Drugs	Signs, symptoms, and treatment	Mechanism/risk factors	(Deleted)						
<u>Riociguat</u>	<u>Ensitrelvir fumaric acid may increase the blood concentration of riociguat. It has been reported that the blood concentration of riociguat was increased and the clearance of riociguat was decreased when co-administered with ketoconazole.</u>	<u>It is considered that the clearance of riociguat is decreased by the inhibitory activity of ensitrelvir fumaric acid against CYP3A and P-glycoprotein/BCRP.</u>							
10.2 Precautions for Co-administration (This drug should be administered with caution when co-administered with the following.) (N/A)			10.2 Precautions for Co-administration (This drug should be administered with caution when co-administered with the following.) <table border="1" data-bbox="1128 917 1995 1402"> <thead> <tr> <th data-bbox="1128 917 1328 1018">Drugs</th> <th data-bbox="1328 917 1720 1018">Signs, symptoms, and treatment</th> <th data-bbox="1720 917 1995 1018">Mechanism/risk factors</th> </tr> </thead> <tbody> <tr> <td data-bbox="1128 1018 1328 1402"><u>Riociguat</u></td> <td data-bbox="1328 1018 1720 1402"><u>Ensitrelvir fumaric acid may increase the blood concentration of riociguat. When co-administration with ensitrelvir fumaric acid is necessary, patients should be monitored for their conditions and dose reduction of</u></td> <td data-bbox="1720 1018 1995 1402"><u>The metabolism of riociguat is suppressed by the inhibitory activity of ensitrelvir fumaric acid against CYP3A.</u></td> </tr> </tbody> </table>	Drugs	Signs, symptoms, and treatment	Mechanism/risk factors	<u>Riociguat</u>	<u>Ensitrelvir fumaric acid may increase the blood concentration of riociguat. When co-administration with ensitrelvir fumaric acid is necessary, patients should be monitored for their conditions and dose reduction of</u>	<u>The metabolism of riociguat is suppressed by the inhibitory activity of ensitrelvir fumaric acid against CYP3A.</u>
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		<u>riociguat should be</u> <u>considered as necessary.</u>	
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N/A: Not Applicable. No corresponding language is included in the current PRECAUTIONS.