

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

Venetoclax

May 20, 2025

Therapeutic category

Other antitumor agents

Non-proprietary name

Venetoclax

Safety measure

PRECAUTIONS should be revised.

Revised language is underlined.

Current			Revision		
<p>2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.)</p> <p><Relapsed or refractory chronic lymphocytic leukaemia (including small lymphocytic lymphoma), relapsed or refractory mantle cell lymphoma></p> <p>Patients receiving a strong CYP3A inhibitor (ritonavir, clarithromycin, itraconazole, voriconazole, posaconazole, preparations containing cobicistat, ensitrelvir, <u>or</u> lonafarnib) during the dose escalation phase of this drug</p>			<p>2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.)</p> <p><Relapsed or refractory chronic lymphocytic leukaemia (including small lymphocytic lymphoma), relapsed or refractory mantle cell lymphoma></p> <p>Patients receiving a strong CYP3A inhibitor (ritonavir, clarithromycin, itraconazole, voriconazole, posaconazole, preparations containing cobicistat, ensitrelvir, <u>lonafarnib, or ceritinib</u>) during the dose escalation phase of this drug</p>		
<p>10. INTERACTIONS</p> <p>10.1 Contraindications for Co-administration (Do not co-administer with the following.)</p>			<p>10. INTERACTIONS</p> <p>10.1 Contraindications for Co-administration (Do not co-administer with the following.)</p>		
Drugs	Signs, symptoms, and treatment	Mechanism/risk factors	Drugs	Signs, symptoms, and treatment	Mechanism/risk factors
<p><Relapsed or refractory chronic lymphocytic leukaemia (including small lymphocytic lymphoma) and relapsed or refractory mantle cell lymphoma during the dose escalation phase of this drug></p> <p>Strong CYP3A inhibitor</p> <p>Ritonavir</p> <p>Clarithromycin</p> <p>Itraconazole</p> <p>Voriconazole</p> <p>Posaconazole</p> <p>Preparations containing</p>	<p>The occurrence of tumour lysis syndrome may increase.</p>	<p>These drugs inhibit CYP3A, and therefore the blood concentration of venetoclax may increase.</p>	<p><Relapsed or refractory chronic lymphocytic leukaemia (including small lymphocytic lymphoma) and relapsed or refractory mantle cell lymphoma during the dose escalation phase of this drug></p> <p>Strong CYP3A inhibitor</p> <p>Ritonavir</p> <p>Clarithromycin</p> <p>Itraconazole</p> <p>Voriconazole</p> <p>Posaconazole</p> <p>Preparations containing</p>	<p>The occurrence of tumour lysis syndrome may increase.</p>	<p>These drugs inhibit CYP3A, and therefore the blood concentration of venetoclax may increase.</p>

cobicistat Ensitrelvir Lonafarnib				cobicistat Ensitrelvir Lonafarnib <u>Ceritinib</u>			
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