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

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