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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

Venetoclax

December 8, 2020

Therapeutic category

Other antitumor agents

Non-proprietary name

Venetoclax

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, 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>2. CONTRAINDICATIONS</p> <p>Patients receiving a potent CYP3A inhibitor (ritonavir, clarithromycin, itraconazole, voriconazole, or preparations containing cobicistat) during the dose escalation phase of this drug.</p>			<p>2. CONTRAINDICATIONS</p> <p>Patients receiving a potent CYP3A inhibitor (ritonavir, clarithromycin, itraconazole, voriconazole, <u>posaconazole</u>, or preparations containing cobicistat) during the dose escalation phase of this drug.</p>		
<p>10. INTERACTIONS</p> <p>10.1 Contraindications for Co-administration</p>			<p>10. INTERACTIONS</p> <p>10.1 Contraindications for Co-administration</p>		
Drugs	Signs, symptoms, and treatment	Mechanism/risk factors	Drugs	Signs, symptoms, and treatment	Mechanism/risk factors
<p>Potent CYP3A inhibitors during the dose escalation phase of this drug</p> <p>(ritonavir, clarithromycin, itraconazole, voriconazole, or preparations containing cobicistat)</p>	<p>The risk of tumor lysis syndrome may be increased.</p>	<p>Blood concentration of this drug may increase due to inhibition of CYP3A by these drugs.</p>	<p>Potent CYP3A inhibitors during the dose escalation phase of this drug</p> <p>(ritonavir, clarithromycin, itraconazole, voriconazole, <u>posaconazole</u>, or preparations containing cobicistat)</p>	<p>The risk of tumor lysis syndrome may be increased.</p>	<p>Blood concentration of this drug may increase due to inhibition of CYP3A by these drugs.</p>
<p>10.2 Precautions for Co-administration</p>			<p>10.2 Precautions for Co-administration</p>		
Drugs	Signs, symptoms, and treatment	Mechanism/risk factors	Drugs	Signs, symptoms, and treatment	Mechanism/risk factors
<p>Potent CYP3A inhibitors during the maintenance phase of this drug</p>	<p>Adverse reactions to this drug may be increased. Doses of this drug should be reduced and patients should be</p>	<p>Blood concentration of this drug may increase due to inhibition of CYP3A by these drugs,</p>	<p>Potent CYP3A inhibitors during the maintenance phase of</p>	<p>Adverse reactions to this drug may be increased. Doses of this drug should be reduced</p>	<p>Blood concentration of this drug may increase due to inhibition of CYP3A by these drugs,</p>

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(such as clarithromycin, itraconazole, or voriconazole)	closely monitored for any signs of adverse reactions.	etc.	this drug (such as clarithromycin, itraconazole, voriconazole, or <u>posaconazole</u>)	and patients should be closely monitored for any signs of adverse reactions.	etc.
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