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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

Suvorexant

December 17, 2021

Therapeutic category

Other agents affecting central nervous system

Non-proprietary name

Suvorexant

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, 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>Contraindications</p> <p>Patients receiving drugs that strongly inhibit CYP3A (itraconazole, clarithromycin, ritonavir, nelfinavir, voriconazole)</p>			<p>Contraindications</p> <p>Patients receiving drugs that strongly inhibit CYP3A (itraconazole, <u>posaconazole</u>, clarithromycin, ritonavir, nelfinavir, voriconazole)</p>		
<p>Drug Interactions</p> <p>Contraindications for Co-Administration</p>			<p>Drug Interactions</p> <p>Contraindications for Co-Administration</p>		
Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors	Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors
<p>Drugs that strongly inhibit CYP3A (itraconazole, clarithromycin, ritonavir, nelfinavir, voriconazole)</p>	<p>These drugs should not be co-administered since they may enhance the effects of this drug markedly.</p>	<p>These drugs strongly inhibit CYP3A, the metabolic enzymes of suvorexant and markedly increase the plasma concentration of suvorexant.</p>	<p>Drugs that strongly inhibit CYP3A (itraconazole, <u>posaconazole</u>, clarithromycin, ritonavir, nelfinavir, voriconazole)</p>	<p>These drugs should not be co-administered since they may enhance the effects of this drug markedly.</p>	<p>These drugs strongly inhibit CYP3A, the metabolic enzymes of suvorexant and markedly increase the plasma concentration of suvorexant.</p>

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