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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 Triazolam

July 20, 2022

**Therapeutic category** 

Hypnotics and sedatives, antianxietics

Non-proprietary name

Triazolam

Safety measure Precautions should be revised.

Pharmaceuticals and Medical Devices Agency

Current			Revision		
Contraindications			Contraindications		
Patients receiving the following drugs: Itraconazole, fluconazole,			Patients receiving the following drugs: Itraconazole, posaconazole,		
fosfluconazole, voriconazole, miconazole, HIV protease inhibitors			fluconazole, fosfluconazole, voriconazole, miconazole, HIV		
(indinavir, ritonavir, etc.), efavirenz, telaprevir			protease inhibitors (indinavir, ritonavir, etc.), efavirenz, telaprevir		
(N/A)			Patients who have experienced abnormal behavior as parasomnia (somnambulism, etc.) with administration of this drug [Parasomnia leading to serious self/other-injuries, accidents, etc. may occur.]		
Interactions			Interactions		
Contraindications for Co-administration			Contraindications for Co-administration		
Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors	Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors
Itraconazole,	The blood	Since this drug and	Itraconazole,	The blood	Since this drug and
fluconazole,	concentration of this	the drugs listed on	posaconazole,	concentration of this	the drugs listed on
fosfluconazole,	drug may rise. The	the left-hand side are	fluconazole,	drug may rise. The	the left-hand side are
voriconazole,	effects may be	metabolized by the	fosfluconazole,	effects may be	metabolized by the
miconazole, HIV	enhanced, and the	same enzyme	voriconazole,	enhanced, and the	same enzyme
protease inhibitors	duration of effects	(CYP3A4), the	miconazole, HIV	duration of effects	(CYP3A4), the
(indinavir, ritonavir,	may be prolonged.	metabolism of this	protease inhibitors	may be prolonged.	metabolism of this
etc.), efavirenz,		drug is inhibited.	(indinavir, ritonavir,		drug is inhibited.
telaprevir			etc.), efavirenz,		

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.

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	telaprevir			
Adverse Reactions	Adverse Reactions			
Clinically Significant Adverse Reactions	Clinically Significant Adverse Reactions			
Psychiatric symptom:	Psychiatric symptom:			
Psychiatric symptoms such as stimulated excitement, confusion,	Psychiatric symptoms such as stimulated excitement, confusion,			
aggression, somnambulism, hallucination, delusion, and agitation	aggression, hallucination, delusion, and agitation may occur.			
may occur. Patients should be carefully monitored. If any	Patients should be carefully monitored. If any abnormalities are			
abnormalities are observed, administration of this drug should be	observed, administration of this drug should be discontinued.			
discontinued.				
	Transient anterograde amnesia, twilight state, parasomnia			
Transient anterograde amnesia, twilight state:	<u>(somnambulism, etc.):</u>			
Transient anterograde amnesia (failure to remember events during	Transient anterograde amnesia (failure to remember events during			
nocturnal awakening) and twilight state may occur. Careful	nocturnal awakening), twilight state, and parasomnia			
administration of this drug is required, such as starting with a low	(somnambulism, etc.) may occur. Careful administration of this dru			
dose. There have been reports of patients driving, eating, etc.	is required, such as starting with a low dose. There have been			
without being fully awake and not remembering the events. If any	reports of patients driving, eating, etc. without being fully awake			
abnormalities are observed, administration of this drug should be	and not remembering the events. If any abnormalities are			
discontinued.	observed, administration of this drug should be discontinued.			

N/A: Not Applicable. No corresponding language is included in the current Precautions.

Pharmaceuticals and Medical Devices Agency

Revision Current 2. CONTRAINDICATIONS 2. CONTRAINDICATIONS Patients receiving the following drugs: Itraconazole, fluconazole, Patients receiving the following drugs: Itraconazole, posaconazole, fluconazole, fosfluconazole, voriconazole, miconazole. HIV fosfluconazole, voriconazole, miconazole, HIV protease inhibitors (indinavir, ritonavir, etc.), efavirenz, telaprevir protease inhibitors (indinavir, ritonavir, etc.), efavirenz, telaprevir (N/A) Patients who have experienced abnormal behavior as parasomnia (somnambulism, etc.) with administration of this drug [Parasomnia leading to serious self/other-injuries, accidents, etc. may occur.] **10. INTERACTIONS 10. INTERACTIONS** 10.1 Contraindications for Co-administration 10.1 Contraindications for Co-administration Drugs Signs, Symptoms, Mechanism and Risk Signs, Symptoms, Mechanism and Drugs and Treatment Factors and Treatment **Risk Factors** Since this drug and Itraconazole, The blood Itraconazole, The blood Since this drug and the drugs listed on the drugs listed on fluconazole. concentration of this posaconazole, concentration of this drug may rise. The drug may rise. The fosfluconazole, the left-hand side are fluconazole, the left-hand side are effects may be effects may be voriconazole, metabolized by the fosfluconazole, metabolized by the miconazole, HIV enhanced, and the enhanced, and the same enzyme voriconazole. same enzyme duration of effects duration of effects protease inhibitors (CYP3A4), the miconazole, HIV (CYP3A4), the may be prolonged. metabolism of this may be prolonged. metabolism of this (indinavir, ritonavir, protease inhibitors etc.), efavirenz, drug is inhibited. (indinavir, ritonavir drug is inhibited. etc.), efavirenz, telaprevir

Revision in line with the Instructions for Electronic Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0611-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions): Revised language is underlined.

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	telaprevir			
11. ADVERSE REACTIONS	11. ADVERSE REACTIONS			
11.1 Clinically Significant Adverse Reactions	11.1 Clinically Significant Adverse Reactions			
Psychiatric symptom	Psychiatric symptom			
Psychiatric symptoms such as stimulated excitement, confusion,	Psychiatric symptoms such as stimulated excitement, confusion,			
aggression, somnambulism, hallucination, delusion, and agitation	aggression, hallucination, delusion, and agitation may occur.			
may occur.				
Transient anterograde amnesia, twilight state	Transient anterograde amnesia, twilight state, <u>parasomnia</u>			
Careful administration of this drug is required, such as starting with	<u>(somnambulism, etc.)</u>			
a low dose. There have been reports of patients driving, eating, etc.	Careful administration of this drug is required, such as starting with			
without being fully awake and not remembering the events.	a low dose. There have been reports of patients driving, eating, etc.			
	without being fully awake and not remembering the events.			

N/A: Not Applicable. No corresponding language

Pharmaceuticals and Medical Devices Agency