

Published by
Ministry of Health, Labour and Welfare



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, antianxiotics

Non-proprietary name

Triazolam

Safety measure

Precautions should be revised.

Pharmaceuticals and Medical Devices Agency

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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 the following drugs: Itraconazole, fluconazole, fosfluconazole, voriconazole, miconazole, HIV protease inhibitors (indinavir, ritonavir, etc.), efavirenz, telaprevir</p> <p>(N/A)</p>			<p>Contraindications</p> <p>Patients receiving the following drugs: Itraconazole, <u>posaconazole</u>, fluconazole, fosfluconazole, voriconazole, miconazole, HIV protease inhibitors (indinavir, ritonavir, etc.), efavirenz, telaprevir</p> <p><u>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.]</u></p>		
<p>Interactions</p> <p>Contraindications for Co-administration</p>			<p>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
Itraconazole, fluconazole, fosfluconazole, voriconazole, miconazole, HIV protease inhibitors (indinavir, ritonavir, etc.), efavirenz, telaprevir	The blood concentration of this drug may rise. The effects may be enhanced, and the duration of effects may be prolonged.	Since this drug and the drugs listed on the left-hand side are metabolized by the same enzyme (CYP3A4), the metabolism of this drug is inhibited.	Itraconazole, <u>posaconazole</u> , fluconazole, fosfluconazole, voriconazole, miconazole, HIV protease inhibitors (indinavir, ritonavir, etc.), efavirenz,	The blood concentration of this drug may rise. The effects may be enhanced, and the duration of effects may be prolonged.	Since this drug and the drugs listed on the left-hand side are metabolized by the same enzyme (CYP3A4), the metabolism of this drug is inhibited.

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<p>Adverse Reactions</p> <p>Clinically Significant Adverse Reactions</p> <p>Psychiatric symptom:</p> <p>Psychiatric symptoms such as stimulated excitement, confusion, aggression, <u>somnambulism</u>, hallucination, delusion, and agitation may occur. Patients should be carefully monitored. If any abnormalities are observed, administration of this drug should be discontinued.</p> <p>Transient anterograde amnesia, twilight state:</p> <p>Transient anterograde amnesia (failure to remember events during nocturnal awakening) and twilight state may occur. Careful administration of this drug is required, such as starting with a low dose. There have been reports of patients driving, eating, etc. without being fully awake and not remembering the events. If any abnormalities are observed, administration of this drug should be discontinued.</p>	<table border="1" data-bbox="1131 153 1982 199"> <tr> <td data-bbox="1131 153 1411 199">telaprevir</td> <td data-bbox="1411 153 1691 199"></td> <td data-bbox="1691 153 1982 199"></td> </tr> </table> <p>Adverse Reactions</p> <p>Clinically Significant Adverse Reactions</p> <p>Psychiatric symptom:</p> <p>Psychiatric symptoms such as stimulated excitement, confusion, aggression, hallucination, delusion, and agitation may occur. Patients should be carefully monitored. If any abnormalities are observed, administration of this drug should be discontinued.</p> <p>Transient anterograde amnesia, twilight state, <u>parasomnia</u> (<u>somnambulism, etc.</u>):</p> <p>Transient anterograde amnesia (failure to remember events during nocturnal awakening), twilight state, <u>and parasomnia</u> (<u>somnambulism, etc.</u>) may occur. Careful administration of this drug is required, such as starting with a low dose. There have been reports of patients driving, eating, etc. without being fully awake and not remembering the events. If any abnormalities are observed, administration of this drug should be discontinued.</p>	telaprevir		
telaprevir				

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

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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.

Current			Revision		
<p>2. CONTRAINDICATIONS</p> <p>Patients receiving the following drugs: Itraconazole, fluconazole, fosfluconazole, voriconazole, miconazole, HIV protease inhibitors (indinavir, ritonavir, etc.), efavirenz, telaprevir</p> <p>(N/A)</p>			<p>2. CONTRAINDICATIONS</p> <p>Patients receiving the following drugs: Itraconazole, <u>posaconazole</u>, fluconazole, fosfluconazole, voriconazole, miconazole, HIV protease inhibitors (indinavir, ritonavir, etc.), efavirenz, telaprevir</p> <p><u>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.]</u></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 and Risk Factors	Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors
Itraconazole, fluconazole, fosfluconazole, voriconazole, miconazole, HIV protease inhibitors (indinavir, ritonavir, etc.), efavirenz, telaprevir	The blood concentration of this drug may rise. The effects may be enhanced, and the duration of effects may be prolonged.	Since this drug and the drugs listed on the left-hand side are metabolized by the same enzyme (CYP3A4), the metabolism of this drug is inhibited.	Itraconazole, <u>posaconazole</u> , fluconazole, fosfluconazole, voriconazole, miconazole, HIV protease inhibitors (indinavir, ritonavir, etc.), efavirenz,	The blood concentration of this drug may rise. The effects may be enhanced, and the duration of effects may be prolonged.	Since this drug and the drugs listed on the left-hand side are metabolized by the same enzyme (CYP3A4), the metabolism of this drug is inhibited.

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<p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Psychiatric symptom</p> <p>Psychiatric symptoms such as stimulated excitement, confusion, aggression, <u>somnambulism</u>, hallucination, delusion, and agitation may occur.</p> <p>Transient anterograde amnesia, twilight state</p> <p>Careful administration of this drug is required, such as starting with a low dose. There have been reports of patients driving, eating, etc. without being fully awake and not remembering the events.</p>	<table border="1" data-bbox="1128 153 1975 199"> <tr> <td data-bbox="1128 153 1413 199">telaprevir</td> <td data-bbox="1413 153 1693 199"></td> <td data-bbox="1693 153 1975 199"></td> </tr> </table> <p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Psychiatric symptom</p> <p>Psychiatric symptoms such as stimulated excitement, confusion, aggression, hallucination, delusion, and agitation may occur.</p> <p>Transient anterograde amnesia, twilight state, <u>parasomnia</u> (<u>somnambulism, etc.</u>)</p> <p>Careful administration of this drug is required, such as starting with a low dose. There have been reports of patients driving, eating, etc. without being fully awake and not remembering the events.</p>	telaprevir		
telaprevir				

N/A: Not Applicable. No corresponding language

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