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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

Zolpidem tartrate

July 20, 2022

Therapeutic category

Hypnotics and sedatives, antianxietics

Non-proprietary name

Zolpidem tartrate

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 (N/A)</p>	<p>Contraindications <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>Adverse Reactions Clinically Significant Adverse Reactions Psychiatric symptom, disturbed consciousness: Psychiatric symptoms or disturbed consciousness such as delirium, confusion, <u>somnambulism</u>, hallucination, excitement, disinhibition, and depressed level of consciousness 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: Transient anterograde amnesia (failure to remember events before falling asleep or during nocturnal awakening after taking this drug) and twilight state may occur. Patients should be put to bed immediately after taking this drug, and caution should be exercised to not wake them up while asleep. There have been reports of patients driving, eating, etc. without being fully awake and not</p>	<p>Adverse Reactions Clinically Significant Adverse Reactions Psychiatric symptom, disturbed consciousness: Psychiatric symptoms or disturbed consciousness such as delirium, confusion, hallucination, excitement, disinhibition, and depressed level of consciousness 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 (somnambulism, etc.)</u>: Transient anterograde amnesia (failure to remember events before falling asleep or during nocturnal awakening after taking this drug), twilight state, and <u>parasomnia (somnambulism, etc.)</u> may occur. Patients should be put to bed immediately after taking this drug, and caution should be exercised to not wake them up while asleep.</p>

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remembering the events. If any abnormalities are observed, administration of this drug should be discontinued.	There have been reports of patients driving, eating, etc. without being fully awake and not remembering the events. <u>In addition, there have also been reports of serious self/other-injuries, accidents, etc. including death.</u> If any abnormalities are observed, administration of this drug should be discontinued.
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N/A: Not Applicable. No corresponding language is included in the current Precautions.

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 (N/A)</p>	<p>2. CONTRAINDICATIONS <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>11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions Psychiatric symptom, disturbed consciousness Psychiatric symptoms or disturbed consciousness such as delirium, confusion, <u>somnambulism</u>, hallucination, excitement, disinhibition, and depressed level of consciousness may occur.</p> <p>Transient anterograde amnesia, twilight state Patients should be put to bed immediately after taking this drug,</p>	<p>11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions Psychiatric symptom, disturbed consciousness Psychiatric symptoms or disturbed consciousness such as delirium, confusion, hallucination, excitement, disinhibition, and depressed level of consciousness may occur.</p> <p>Transient anterograde amnesia, twilight state, <u>parasomnia (somnambulism, etc.)</u></p>

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