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Translated by  
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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

## Zopiclone

July 20, 2022

### **Therapeutic category**

Hypnotics and sedatives, antianxiotics

### **Non-proprietary name**

Zopiclone

### **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 hallucination, delirium, confusion, <u>somnambulism</u>, nightmare, irritability, aggression, and abnormal behavior 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 during nocturnal awakening, etc.) 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</p>	<p>Adverse Reactions Clinically Significant Adverse Reactions Psychiatric symptom, disturbed consciousness: Psychiatric symptoms or disturbed consciousness such as hallucination, delirium, confusion, nightmare, irritability, aggression, and abnormal behavior 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 during nocturnal awakening, etc.), twilight state, <u>and parasomnia (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</p>

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discontinued.	and not remembering the events. 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 Hallucination, delirium, confusion, <u>somnambulism</u>, nightmare, irritability, aggression, abnormal behavior, etc. may occur.</p> <p>Transient anterograde amnesia, twilight state 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>	<p>11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions Psychiatric symptom, disturbed consciousness Hallucination, delirium, confusion, nightmare, irritability, aggression, abnormal behavior, etc. may occur.</p> <p>Transient anterograde amnesia, twilight state, <u>parasomnia (somnambulism, etc.)</u> 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>

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