

This document is an English-translated version of an attachment of a notification for Revision of PRECAUTIONS issued by the Ministry of Health, Labour and Welfare.

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

Carbamazepine

March 17, 2026

Therapeutic category

Antiepileptics

Psychotropic agents

Non-proprietary name

Carbamazepine

Safety measure

PRECAUTIONS should be revised.

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Revised language is underlined.

Current	Revision
<p>8. IMPORTANT PRECAUTIONS</p> <p>< Common to all indications ></p> <p><u>As symptoms such as somnolence and decreased attention/concentration/reflex motor capacity, etc. may occur, caution patients not to engage in hazardous machine operations such as driving a car during treatment.</u></p> <p>< Psychomotor seizure, mental disorder associated with epileptic personality or epilepsy, epileptic convulsive seizure: tonic-clonic seizure (generalized convulsive seizure, grand mal) ></p> <p>(N/A)</p> <p>(N/A)</p>	<p>8. IMPORTANT PRECAUTIONS</p> <p>< Common to all indications ></p> <p>(deleted)</p> <p>< Psychomotor seizure, mental disorder associated with epileptic personality or epilepsy, epileptic convulsive seizure: tonic-clonic seizure (generalized convulsive seizure, grand mal) ></p> <p><u>Somnolence and decreased attention/concentration/reflex motor capacity, etc. may occur. The appropriateness of performing hazardous machine operations such as driving a car should be carefully determined by a physician based on a full understanding of the points to consider provided by relevant academic societies. Patients should be appropriately instructed that, if they perform hazardous machine operations, they should be very careful when performing such operations. Patients should also be instructed that, if they experience somnolence, etc., they should not engage in hazardous machine operations such as driving a car.</u></p> <p>< <u>Mania, manic state in manic depressive illness, excitement in</u></p>

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	<p><u>schizophrenia, and trigeminal neuralgia ></u> <u>As symptoms such as somnolence and decreased</u> <u>attention/concentration/reflex motor capacity, etc. may occur, caution</u> <u>patients not to engage in hazardous machine operations such as</u> <u>driving a car during treatment.</u></p>
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Note: Carbamazepine is designated as a drug requiring preparation of a Drug Guide for Patients.

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