

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

Lamotrigine

March 17, 2026

Therapeutic category

Antiepileptics

Psychotropic agents

Non-proprietary name

Lamotrigine

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>< Treatment of various types of epilepsy > (N/A)</p> <p>(N/A)</p>	<p>8. IMPORTANT PRECAUTIONS</p> <p>< Common to all indications ></p> <p>(deleted)</p> <p>< Treatment of various types of epilepsy ></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>< Suppression of recurrent/relapsed mood episodes in patients with bipolar disorder ></p> <p><u>As symptoms such as somnolence and decreased</u></p>

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