

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

Sodium valproate

March 17, 2026

Therapeutic category

Antiepileptics

Psychotropic agents

Non-proprietary name

Sodium valproate

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 and personality or behaviour disorder associated with epilepsy></p> <p>(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 and personality or behaviour disorder associated with 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><u>< Treatment of mania, manic state in manic depressive illness, prevention of migraine attacks ></u></p> |

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