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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

Topiramate

February 15, 2024

Therapeutic category

Antiepileptics

Non-proprietary name

Topiramate

Safety measure

PRECAUTIONS should be revised.

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

Revision in line with the Instructions for Electronic Package Inserts of Prescription Drugs, PSEHB Notification No. 0611-1 by the Director-General of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions):

Revised language is underlined.

Current	Revision
<p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS (N/A)</p> <p>9.5 Pregnant Women Pregnant women or women who may be pregnant should be administered this drug only if the potential therapeutic benefits (prevention of frequent epileptic seizures in mothers and protection of foetuses from hypoxia) are considered to outweigh the potential risks.</p> <p>(N/A)</p>	<p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p><u>9.4 Patients with Reproductive Potential</u></p> <p><u>When this drug is used in women of child-bearing potential, the patients should be fully informed of the risks that may occur in infants/children born to topiramate-exposed mothers.</u></p> <p>9.5 Pregnant Women Pregnant women or women who may be pregnant should be administered this drug only if the potential therapeutic benefits (prevention of frequent epileptic seizures in mothers and protection of foetuses from hypoxia) are considered to outweigh the potential risks. <u>When this drug is used during pregnancy, or when the women become pregnant while on treatment with this drug, the patients should be fully informed of the risks that may occur in infants/children born to topiramate-exposed mothers. It has been reported as follows.</u></p> <p><u>A possible relationship between the infants/children born to topiramate-exposed mothers and the occurrence of</u></p>

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	<u>neurodevelopmental disorder (autism spectrum disorder, intellectual development disorder, and attention deficit hyperactivity disorder) has been reported in the observational studies performed overseas.</u>
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[References] Bjørk MH, et al.:JAMA Neurol. 2022; 79(7): 672-681.

Dreier JW, et al.:JAMA Neurol. 2023; 80(6): 568-577.

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

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