

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

Aceneuramic acid

November 13, 2024

Therapeutic category

Other agents affecting nervous system and sensory organs

Non-proprietary name

Aceneuramic acid

Safety measure

PRECAUTIONS should be revised.

Revised language is underlined.

Current	Revision
<p><u>8. IMPORTANT PRECAUTIONS</u></p> <p><u>This drug should be administered after fully explaining to patients that impurities for which genotoxic potential has not been elucidated are contained and obtaining the understanding of the patients.</u></p>	<p>(deleted)</p>
<p>15. OTHER PRECAUTIONS</p> <p><u>15.2 Information Based on Nonclinical Studies</u></p> <p><u>Genotoxicity studies on impurities for which genotoxicity evaluation is required have not been conducted.</u></p>	<p>15. OTHER PRECAUTIONS</p> <p>(deleted)</p>