

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

Cytarabine

Daunorubicin hydrochloride

February 10, 2026

Therapeutic category

Antimetabolic agents

Antitumor antibiotics and preparations

Non-proprietary name

Cytarabine

Daunorubicin hydrochloride

Safety measure

PRECAUTIONS should be revised.

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Revised language is underlined.

Current	Revision
<p>8. IMPORTANT PRECAUTIONS (newly added)</p> <p>11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (newly added)</p>	<p>8. IMPORTANT PRECAUTIONS <u>Tumour lysis syndrome may occur. Patients should be carefully monitored by checking serum electrolyte levels, renal function, etc.</u></p> <p>11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions <u>Tumour lysis syndrome</u> <u>If any abnormalities are observed, administration of this drug should be discontinued, appropriate measures (e.g., administration of physiological saline solution and/or hyperuricaemia therapeutic agents, and dialysis) should be taken, and patients should be carefully monitored until recovery from such symptoms.</u></p>

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