

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

Gemcitabine hydrochloride

December 17, 2024

Therapeutic category

Antimetabolic agents

Non-proprietary name

Gemcitabine hydrochloride

Safety measure

PRECAUTIONS should be revised.

Revised language is underlined.

Current	Revision
<p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Skin disorders</p> <p><u>Serious</u> skin disorders such as erythema, blister, or desquamation may occur.</p>	<p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p><u>Severe</u> skin disorders</p> <p><u>Severe</u> skin disorders such as <u>toxic epidermal necrolysis (TEN),</u> <u>oculomucocutaneous syndrome (Stevens-Johnson syndrome),</u> erythema, blister, or desquamation may occur.</p>