

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.

Attachment 2
August 25, 2026

【Therapeutic category】 117 Psychotropic agents
239 Other agents affecting digestive organs

【Non-proprietary name】 Olanzapine (oral dosage form)

【Safety measure】 PRECAUTIONS should be revised.

A revised description is underlined.

Current	Revision
1. WARNINGS N/A	1. WARNINGS < <u>Gastrointestinal symptoms (nausea and vomiting) associated with chemotherapy medicine (such as cisplatin) for cancer</u> > <u>This drug should not be administered to patients with diabetes mellitus or a history of diabetes mellitus unless the potential therapeutic benefits are considered to outweigh the potential risks. Patients should be continuously monitored through such methods as frequent blood glucose monitoring each day before and during administration of this drug and continuous monitoring until blood glucose levels become stable after administration of this drug has ended, and this drug should be administered after establishing a system that enables an adequate response in emergencies throughout the administration period.</u>

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.

2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.) Patients with diabetes mellitus or a history of diabetes mellitus 9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.1 Patients with Complications or a History of Diseases, etc. N/A	2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.) <u>< Schizophrenia and improvement of manic symptoms and depressive symptoms in bipolar disorder ></u> Patients with diabetes mellitus or a history of diabetes mellitus 9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.1 Patients with Complications or a History of Diseases, etc. <u>< Gastrointestinal symptoms (nausea and vomiting) associated with chemotherapy medicine (such as cisplatin) for cancer ></u> <u>Patients with diabetes mellitus or a history of diabetes mellitus</u> <u>The following points should be noted. Administration of this drug may increase blood glucose levels and rapidly worsen the metabolic state. This drug should be administered after establishing a system that enables an adequate response in emergencies throughout the administration period.</u> <u>• This drug should be administered only to patients with good glycaemic control. The necessity of this drug should be judged according to the patient's condition with reference to the latest guidelines of related academic societies, etc.</u> <u>• The dose and duration of administration of this drug should be limited to the minimum necessary.</u> <u>• Patients should be continuously monitored through such methods as</u>
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	<u>frequent blood glucose monitoring each day before and during administration of this drug and continuous monitoring until blood glucose levels become stable after administration of this drug has ended.</u>
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N/A: Not Applicable. No corresponding description is included in the current PRECAUTIONS.

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