

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

Semaglutide (genetical recombination) Tirzepatide Insulin glargine (genetical recombination)/lixisenatide

July 30, 2025

Therapeutic category

Other hormone preparations (including antihormone preparations)

Antidiabetic agents

Non-proprietary name

Semaglutide (genetical recombination)

Tirzepatide

Insulin glargine (genetical recombination)/lixisenatide

Safety measure

PRECAUTIONS should be revised.

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Revised language is underlined.

Current	Revision
9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.1 Patients with Complication or History of Diseases, etc. (N/A)	9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.1 Patients with Complication or History of Diseases, etc. <u>Patients with a medical history of abdominal surgery or ileus</u> <u>Ileus, including intestinal obstruction, may occur.</u>
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (N/A)	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions <u>Ileus</u> <u>Ileus, including intestinal obstruction, may occur. If any abnormalities</u> <u>such as severe constipation, abdominal distension, persistent</u> <u>abdominal pain, or vomiting are observed, administration of this drug</u> <u>should be discontinued, and appropriate measures should be taken.</u>

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