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Translated by
Pharmaceuticals and Medical Devices Agency



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

Tirzepatide

February 14, 2023

Therapeutic category

Other hormone preparations (including antihormone preparations)

Non-proprietary name

Tirzepatide

Safety measure

Precautions should be revised.

Pharmaceuticals and Medical Devices Agency

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Revision in line with the Instructions for Electronic Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0611-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions): Revised language is underlined.

Current	Revision
<p>8. IMPORTANT PRECAUTIONS</p> <p><u>Acute gallbladder disease such as cholecystitis and cholelithiasis</u> may occur. If abdominal symptoms such as abdominal pain are observed, appropriate measures should be taken with consideration given to a close examination of the cause by imaging tests, etc., if necessary.</p> <p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>(N/A)</p>	<p>8. IMPORTANT PRECAUTIONS</p> <p><u>Cholelithiasis, cholecystitis, cholangitis, or cholestatic jaundice</u> may occur. If abdominal symptoms such as abdominal pain are observed, appropriate measures should be taken with consideration given to close examination of the cause by imaging tests, etc., if necessary.</p> <p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p><u>Cholecystitis, cholangitis, cholestatic jaundice</u></p>

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

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