

*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

Teneligliptin hydrobromide hydrate/canagliflozin hydrate

December 17, 2024

Therapeutic category

Antidiabetic agents

Non-proprietary name

Teneligliptin hydrobromide hydrate/canagliflozin hydrate

Safety measure

PRECAUTIONS should be revised.

Revised language is underlined.

Current	Revision
<p data-bbox="237 260 645 288">8. IMPORTANT PRECAUTIONS</p> <p data-bbox="264 309 1106 531">Fatty acid metabolism may be elevated and ketosis may occur leading to ketoacidosis, even in cases with well-controlled blood glucose levels. This is due to the urinary glucose excretion-enhancing activity, which is the mechanism of action of canagliflozin, the active ingredient of this drug.</p> <p data-bbox="293 552 360 580">(N/A)</p>	<p data-bbox="1131 260 1538 288">8. IMPORTANT PRECAUTIONS</p> <p data-bbox="1158 309 2000 531">Fatty acid metabolism may be elevated and ketosis may occur leading to ketoacidosis, even in cases with well-controlled blood glucose levels. This is due to the urinary glucose excretion-enhancing activity, which is the mechanism of action of canagliflozin, the active ingredient of this drug.</p> <p data-bbox="1184 552 2000 770"><u>Cases have been reported in which urinary glucose excretion and ketoacidosis persisted longer than expected from the plasma half-life of the drug, after discontinuing administration of SGLT2 inhibitors including canagliflozin. Patients should be carefully monitored, with as-needed urinary glucose measurements, etc.</u></p>

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