

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

Empagliflozin, Dapagliflozin propylene glycolate hydrate Ipragliflozin L-proline, Canagliflozin hydrate Tofogliflozin hydrate, Luseogliflozin hydrate

December 17, 2024

Therapeutic category

Other cardiovascular agents

Antidiabetic agents

Agents affecting metabolism, n.e.c. (not elsewhere classified)

Non-proprietary name

Empagliflozin

Dapagliflozin propylene glycolate hydrate

Ipragliflozin L-proline

Canagliflozin hydrate

Tofogliflozin hydrate

Luseogliflozin hydrate

Safety measure

PRECAUTIONS should be revised.

Revised language is underlined.

Current	Revision
<p>8. IMPORTANT PRECAUTIONS</p> <p>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 this drug.</p> <p>(N/A)</p>	<p>8. IMPORTANT PRECAUTIONS</p> <p>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 this drug.</p> <p><u>Cases have been reported in which urinary glucose excretion and ketoacidosis persisted longer than expected from plasma half-lives of the drugs, after discontinuing administration of SGLT2 inhibitors including this drug. 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.