

*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

## Sitagliptin phosphate hydrate/ipragliflozin L-proline

December 17, 2024

### **Therapeutic category**

Antidiabetic agents

### **Non-proprietary name**

Sitagliptin phosphate hydrate/ipragliflozin L-proline

### **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 ipragliflozin.</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 ipragliflozin.</p> <p><u>Cases have been reported in which urinary glucose excretion and ketoacidosis persisted longer than expected from the plasma half-lives of the drugs, after discontinuing administration of SGLT2 inhibitors including ipragliflozin. 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.