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*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

May 9, 2019

### **Therapeutic category**

Antidiabetic agents

### **Non-proprietary name**

Sitagliptin phosphate hydrate/ipragliflozin L-proline

### **Safety measure**

Precautions should be revised in the package insert.

**Pharmaceuticals and Medical Devices Agency**

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Revision in line with the Instructions for Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director General of Pharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions): Revised language is underlined.

Current	Revision
<p><b>Important Precautions</b></p> <p>Urinary tract infection may occur by administration of ipragliflozin, which may lead to serious infections such as pyelonephritis and sepsis. <u>Genital infection such as vaginal candidiasis may also occur.</u> Patients should be carefully monitored for urinary tract infection and genital infection. If such infections occur, appropriate measures should be taken, and measures such as temporary discontinuation of this drug should be considered based on the patient's condition. Symptoms and management of urinary tract infection and genital infection should be explained to patients.</p> <p><b>Adverse Reactions</b></p> <p><b>Clinically Significant Adverse Reactions</b></p> <p>Pyelonephritis, sepsis:</p> <p>Pyelonephritis may occur, which may lead to sepsis (including septic shock). Patients should be carefully monitored. If any abnormalities are observed, administration of this drug should be discontinued, and appropriate measures should be taken.</p>	<p><b>Important Precautions</b></p> <p>Urinary tract infection <u>and genital infection</u> may occur by administration of ipragliflozin, which may lead to serious infections such as pyelonephritis, <u>necrotising fasciitis of the external genitalia and perineum (Fournier's gangrene),</u> and sepsis. Patients should be carefully monitored for urinary tract infection and genital infection. If such infections occur, appropriate measures should be taken, and measures such as temporary discontinuation of this drug should be considered based on the patient's condition. Symptoms and management of urinary tract infection and genital infection should be explained to patients.</p> <p><b>Adverse Reactions</b></p> <p><b>Clinically Significant Adverse Reactions</b></p> <p>Pyelonephritis, <u>necrotising fasciitis of the external genitalia and perineum (Fournier's gangrene),</u> sepsis:</p> <p>Pyelonephritis, <u>necrotising fasciitis of the external genitalia and perineum (Fournier's gangrene)</u> may occur, which may lead to sepsis (including septic shock). Patients should be carefully monitored. If any abnormalities are observed, administration of this drug should be discontinued, and appropriate measures should be taken.</p>

**Pharmaceuticals and Medical Devices Agency**

Revision in line with the Instructions for Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0608-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 8, 2017(New instructions): Revised language is underlined.

Current	Revision
<p><b>8. IMPORTANT PRECAUTIONS</b></p> <p>Urinary tract infection may occur by administration of ipragliflozin, which may lead to serious infections such as pyelonephritis and sepsis. <u>Genital infection such as vaginal candidiasis may also occur.</u> Patients should be carefully monitored for urinary tract infection and genital infection. If such infections occur, appropriate measures should be taken, and measures such as temporary discontinuation of this drug should be considered based on the patient's condition. Symptoms and management of urinary tract infection and genital infection should be explained to patients.</p> <p><b>11. ADVERSE REACTIONS</b></p> <p><b>11.1 Clinically Significant Adverse Reactions</b></p> <p>Pyelonephritis, sepsis</p> <p>Pyelonephritis may occur, which may lead to sepsis (including septic shock).</p>	<p><b>8. IMPORTANT PRECAUTIONS</b></p> <p>Urinary tract infection <u>and genital infection</u> may occur by ipragliflozin, which may lead to serious infections such as pyelonephritis, <u>necrotising fasciitis of the external genitalia and perineum (Fournier's gangrene),</u> and sepsis. Patients should be carefully monitored for urinary tract infection and genital infection. If such infections occur, appropriate measures should be taken, and measures such as temporary discontinuation of this drug should be considered based on the patient's condition. Symptoms and management of urinary tract infection and genital infection should be explained to patients.</p> <p><b>11. ADVERSE REACTIONS</b></p> <p><b>11.1 Clinically Significant Adverse Reactions</b></p> <p>Pyelonephritis, <u>necrotising fasciitis of the external genitalia and perineum (Fournier's gangrene),</u> sepsis</p> <p>Pyelonephritis, <u>necrotising fasciitis of the external genitalia and perineum (Fournier's gangrene)</u> may occur, which may lead to sepsis (including septic shock).</p>

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