

*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

## Aliskiren fumarate

September 9, 2025

### **Therapeutic category**

Antihypertensives

### **Non-proprietary name**

Aliskiren fumarate

### **Safety measure**

PRECAUTIONS should be revised.

*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.*

Revised language is underlined.

Current	Revision
<p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Angioedema</p> <p>Symptoms such as dyspnoea, difficult swallowing, and swelling of the face, lip, pharynx, tongue, and limbs may occur.</p>	<p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Angioedema</p> <p>Symptoms such as dyspnoea, difficult swallowing, and swelling of the face, lip, pharynx, tongue, and limbs may occur. <u>Of note, intestinal angioedema accompanied by abdominal pain, queasy, vomiting, diarrhoea, etc. may occur.</u></p>