

*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

## Irbesartan

## Irbesartan/amlodipine besilate

## Irbesartan/trichlormethiazide

September 9, 2025

### **Therapeutic category**

Antihypertensives

### **Non-proprietary name**

Irbesartan

Irbesartan/amlodipine besilate

Irbesartan/trichlormethiazide

### **Safety measure**

PRECAUTIONS should be revised.

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Revised language is underlined.

Current	Revision
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions Angioedema Angioedema with swelling of the face, lip, pharynx, tongue, etc. may occur.	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions Angioedema Angioedema with swelling of the face, lip, pharynx, tongue, etc. may occur. <u>Of note, intestinal angioedema accompanied by abdominal pain, queasy, vomiting, diarrhoea, etc. may occur.</u>