

*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

## Telmisartan

### Telmisartan/amlodipine besilate

### Telmisartan/amlodipine besilate/hydrochlorothiazide

### Telmisartan/hydrochlorothiazide

September 9, 2025

#### **Therapeutic category**

Antihypertensives

#### **Non-proprietary name**

Telmisartan

Telmisartan/amlodipine besilate

Telmisartan/amlodipine besilate/hydrochlorothiazide

Telmisartan/hydrochlorothiazide

#### **Safety measure**

PRECAUTIONS should be revised.

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Revised language is underlined.

Current	Revision
<p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Angioedema</p> <p>Cases of angioedema with swelling of the face, lip, pharynx/larynx, tongue, etc. have been reported, resulting in dyspnoea due to laryngeal oedema, etc.</p>	<p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Angioedema</p> <p>Cases of angioedema with swelling of the face, lip, pharynx/larynx, tongue, etc. have been reported, resulting in dyspnoea due to laryngeal oedema, etc. <u>Of note, intestinal angioedema accompanied by abdominal pain, queasy, vomiting, diarrhoea, etc. may occur.</u></p>