

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/amlodipine besilate/hydrochlorothiazide Telmisartan/hydrochlorothiazide

May 20, 2025

Therapeutic category

Antihypertensives

Non-proprietary name

Telmisartan/amlodipine besilate/hydrochlorothiazide

Telmisartan/hydrochlorothiazide

Safety measure

PRECAUTIONS should be revised.

Revised language is underlined.

Current	Revision
<p>8. IMPORTANT PRECAUTIONS</p> <p>(N/A)</p>	<p>8. IMPORTANT PRECAUTIONS</p> <p><u>Hydrochlorothiazide, which is an ingredient of this drug, may cause acute myopia, angle closure glaucoma, and/or choroidal effusion. Patients should be instructed to consult an ophthalmologist immediately if they experience abnormalities such as a rapid reduction in visual acuity and eye pain.</u></p>
<p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Acute myopia, angle closure glaucoma</p> <p>Acute myopia (including blurred vision and reduced visual acuity) <u>and/or angle closure glaucoma may occur. If abnormalities such as a rapid reduction in visual acuity and eye pain are observed, administration should be discontinued, and the patients should be instructed to consult an ophthalmologist promptly.</u></p>	<p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Acute myopia, angle closure glaucoma, <u>choroidal effusion</u></p> <p>Acute myopia (including blurred vision and reduced visual acuity), <u>angle closure glaucoma, and/or choroidal effusion</u> may occur.</p>

N/A: Not Applicable. No corresponding language is included in the current PRECAUTIONS.