

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

Azilsartan

Azilsartan/amlodipine besilate

Candesartan cilexetil

Candesartan cilexetil/amlodipine besilate

Candesartan cilexetil/hydrochlorothiazide

September 9, 2025

Therapeutic category

Antihypertensives

Vasodilators

Non-proprietary name

Azilsartan

Azilsartan/amlodipine besilate

Candesartan cilexetil

Candesartan cilexetil/amlodipine besilate

Candesartan cilexetil/hydrochlorothiazide

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