

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

Trandolapril

September 9, 2025

Therapeutic category

Antihypertensives

Non-proprietary name

Trandolapril

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>Angioedema accompanied by dyspnoea, with swelling of the face, tongue, glottis, and larynx, may occur. If any abnormalities are observed, administration should be discontinued immediately, and appropriate measures should be taken, such as administering adrenaline injections and maintaining the airway. <u>Occurrences of intestinal angioedema (symptoms: Abdominal pain, queasy, vomiting, diarrhoea, etc.) have been reported with other angiotensin-converting enzyme inhibitors.</u></p>	<p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Angioedema</p> <p>Angioedema accompanied by dyspnoea, with swelling of the face, tongue, glottis, and larynx, may occur. If any abnormalities are observed, administration should be discontinued immediately, and appropriate measures should be taken, such as administering adrenaline injections and maintaining the airway. <u>Of note, intestinal angioedema accompanied by abdominal pain, queasy, vomiting, diarrhoea, etc. may occur.</u></p>