

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

Sacubitril valsartan sodium hydrate

September 9, 2025

Therapeutic category

Antihypertensives

Other cardiovascular agents

Non-proprietary name

Sacubitril valsartan sodium hydrate

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 leading to airway obstruction may occur, with symptoms such as swelling of the tongue, glottis, and larynx. In such cases, administration should be discontinued immediately, and appropriate measures should be taken, such as administering adrenaline injections and maintaining the airway. Administration of this drug should not be resumed even if angioedema resolves.</p>	<p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Angioedema</p> <p>Angioedema leading to airway obstruction may occur, with symptoms such as swelling of the tongue, glottis, and larynx. In such cases, administration should be discontinued immediately, and appropriate measures should be taken, such as administering adrenaline injections and maintaining the airway. Administration of this drug should not be resumed even if angioedema resolves. <u>Of note, intestinal angioedema accompanied by abdominal pain, queasy, vomiting, diarrhoea, etc. may occur.</u></p>