

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

Sorafenib tosilate

December 17, 2024

Therapeutic category

Other antitumor agents

Non-proprietary name

Sorafenib tosilate

Safety measure

PRECAUTIONS should be revised.

Revised language is underlined.

Current	Revision
<p>8. IMPORTANT PRECAUTIONS</p> <p><Common to all indications></p> <p>(N/A)</p> <p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>(N/A)</p>	<p>8. IMPORTANT PRECAUTIONS</p> <p><Common to all indications></p> <p><u>Tumour lysis syndrome may occur. Patients should be carefully monitored by checking serum electrolyte levels, renal function, etc.</u></p> <p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p><u>Tumour lysis syndrome</u></p> <p><u>If any abnormalities are observed, administration of this drug should be discontinued, appropriate measures (e.g., administration of physiological saline solution and/or hyperuricaemia therapeutic agents, and dialysis) should be taken, and patients should be carefully monitored until recovery from such symptoms.</u></p>

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