

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

Regorafenib hydrate

July 17, 2024

Therapeutic category

Other antitumor agents

Non-proprietary name

Regorafenib hydrate

Safety measure

PRECAUTIONS should be revised.

Pharmaceuticals and Medical Devices Agency

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Revised language is underlined.

Current	Revision
<p>8. IMPORTANT PRECAUTIONS</p> <p>Thrombocytopenia may occur. Patients should be carefully monitored through periodic blood tests, etc. during treatment with this drug.</p>	<p>8. IMPORTANT PRECAUTIONS</p> <p>Thrombocytopenia, <u>neutropenia, or leukopenia</u> may occur. Patients should be carefully monitored through periodic blood tests, etc. during treatment with this drug.</p>
<p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Thrombocytopenia</p>	<p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Thrombocytopenia, <u>neutropenia, leukopenia</u></p>

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