

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

Dabrafenib mesilate Trametinib dimethyl sulfoxide

March 5, 2025

Therapeutic category

Other antitumor agents

Non-proprietary name

Dabrafenib mesilate

Trametinib dimethyl sulfoxide

Safety measure

PRECAUTIONS should be revised.

Revised language is underlined.

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

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