

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

Borofalan (¹⁰B)

May 20, 2025

Therapeutic category

Other antitumor agents

Non-proprietary name

Borofalan (¹⁰B)

Safety measure

PRECAUTIONS should be revised.

Revised language is underlined.

Current	Revision
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (N/A)	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions <u>Necrosis, mucosal ulceration, perforation, fistula</u> <u>Mucosal ulceration, perforation, or fistula may occur in association</u> <u>with necrosis at the irradiation site.</u>

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