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Translated by  
Pharmaceuticals and Medical Devices Agency



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*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 (<sup>10</sup>B)

March 23, 2023

### **Therapeutic category**

Other antitumor agents

### **Non-proprietary name**

Borofalan (<sup>10</sup>B)

### **Safety measure**

Precautions should be revised.

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Revision in line with the Instructions for Electronic Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0611-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions): 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>Pharyngolaryngeal oedema</u> <u>Pharyngolaryngeal oedema may occur, resulting in airway stenosis and obstruction.</u>

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

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