独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Summary of Investigation Results

Borofalan (^{10}B)

May 20, 2025

Non-proprietary name

Borofalan (^{10}B)

Brand name (marketing authorization holder)

Steboronine 9000 mg/300 mL for infusion (STELLA PHARMA CORPORATION)

Japanese market launch

May 2020

Indications

Unresectable, locally advanced or recurrent head and neck cancer

Summary of revisions

“Necrosis, mucosal ulceration, perforation, fistula” should be added to the 11.1 Clinically Significant Adverse Reactions section in 11. ADVERSE REACTIONS.

Investigation results and background of the revision

Cases involving perforation-related events in the treatment using this drug and a neutron irradiation medical device for boron neutron capture therapy (hereinafter referred to as "this treatment") were evaluated. Cases for which a causal relationship between this treatment and mucosal ulceration, perforation, or fistula accompanying necrosis caused by this treatment was reasonably possible have been reported. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of PRECAUTIONS, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.

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Reference: Number of cases* and patient mortalities involving perforation-related events reported in Japan

A total of 9 cases have been reported to date (including 5 cases for which a causal relationship between the drug and the event was reasonably possible).

One instance of patient mortality has been reported to date. (A causal relationship between the drug and the death subsequent to the event could not be established for this case.)

*Cases with a description of perforation, fistula, or ulceration in the case report form among those collected in the PMDA's database for adverse drug reactions, etc. reports

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the “Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency” (PMDA Administrative Rule No. 20-8, dated December 25, 2008).