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

Carmustine

Non-proprietary name

Carmustine

Brand name (Marketing authorization holder)

Gliadel for Intracerebral Implant 7.7 mg (Eisai Co., Ltd.)

Indications

Malignant glioma

Summary of revision

Descriptions concerning air accumulation at the implant site should be added to the Important precautions section.

Background of the revision and investigation results

Although a causal relationship with the product was not established, cases of air accumulation at the implant site have been reported in patients treated with carmustine in Japan, and there have been reports of neurological symptoms. Following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan

A total of 17 cases associated with air accumulation at the implant site have been reported (a causal relationship to the product could not be established for these patients). No fatality has been reported.

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