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Summary of investigation results

Vemurafenib

February 14, 2017

Non-proprietary name

Vemurafenib

Brand name (Marketing authorization holder)

Zelboraf Tablet 240 mg (Chugai Pharmaceutical Co., Ltd.)

Indications

BRAF mutation-positive radically unresectable malignant melanoma

Summary of revision

1. Precautions with regards to ‘acute kidney injury’ should be newly added in the Important Precautions section.
2. ‘Acute kidney injury’ should be newly added in the Clinically Significant Adverse Reactions section.

Background of the revision and investigation results

Cases of acute kidney injury have been reported in patients treated with vemurafenib both in Japan and overseas. In addition, the company core data sheet (CCDS)* has been revised. 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 2 cases associated with acute kidney injury have been reported (including 2 cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.

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NOTE:

*CCDS is prepared by the marketing authorization holder and covers material relating to safety, indications, dosing, pharmacology, and other information concerning the product.

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