



Summary of investigation results

Eribulin Mesilate

February 16, 2016

Non-proprietary name

Eribulin Mesilate

Brand name (Marketing authorization holder)

Halaven Injection 1 mg (Eisai Co., Ltd.)

Indications

Unresectable or recurrent breast cancer

Summary of revision

“Oculomucocutaneous syndrome (Stevens-Johnson syndrome) and erythema multiforme” should be newly added in the Clinically significant adverse reaction section.

Background of the revision and investigation results

Cases of oculomucocutaneous syndrome have been reported in patients treated with eribulin mesilate in both Japan and overseas. 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.

Cases of erythema multiforme have been reported in patients treated with this drug overseas. 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.



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.

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

A total of 3 cases of oculomucocutaneous syndrome have been reported (including 2 cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.

No case of erythema multiforme has been reported.