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

Verteporfin

March 22, 2016

Non-proprietary name

Verteporfin

Brand name (Marketing authorization holder)

Visudyne Injection 15 mg (Novartis Pharma K.K.)

Indications

1. Age-related macular degeneration in association with subfoveal choroidal neovascularization

Summary of revision

“Convulsions” should be newly added in the Clinically significant adverse reaction section.

Background of the revision and investigation results

Cases of convulsions have been reported in patients treated with verteporfin both overseas and in Japan. In addition, the company core datasheet (CCDS) has been updated.

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

No case associated with convulsions has been reported.

NOTE:

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

Pharmaceuticals and Medical Devices Agency
Office of Safety I
3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp