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Summary of investigation results

Fingolimod hydrochloride

September 15, 2015

Non-proprietary name

Fingolimod hydrochloride

Brand name (Marketing authorization holder)

Gilenya Capsules 0.5 mg and Imusera Capsules 0.5 mg (Novartis Pharma K.K., Mitsubishi Tanabe Pharma Corporation)

Indications

Prophylaxis of relapse of multiple sclerosis and suppress progression of physical disabilities

Summary of revision

“Progressive multifocal leukoencephalopathy” should be newly added in the Clinically significant adverse reactions section.

Background of the revision and investigation results

Cases of progressive multifocal leukoencephalopathy have been reported in patients treated with fingolimod hydrochloride overseas. In addition, the European Medicines Agency (EMA) has taken action to alert caution, and the United States Package Inserts (USPI) and the company core datasheet (CCDS)* have 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 progressive multifocal leukoencephalopathy has been reported.

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NOTE:

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

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