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Revision of Precautions

Fingolimod hydrochloride

Non-proprietary name

Fingolimod hydrochloride

Safety measure

Precautions should be revised in the package insert.

In the Precautions concerning indications section, the following text should be revised (underlined parts are revised):

The efficacy and safety of this drug for progressive multiple sclerosis has not yet been established. Fingolimod did not slow progression of physical disability in an overseas placebo-controlled study in patients with primary progressive multiple sclerosis.

In the Other precautions section, the following text should be added (underlined parts are revised):

In an overseas placebo-controlled, randomized, double-blind, parallel group comparison study in patients with primary progressive multiple sclerosis, patients were orally administered either fingolimod 0.5 mg or placebo once daily for 36 months (maximum 5 years). No statistically significant difference was noted in time to progression of disability persisting for 3 months, as determined by the composite endpoint based on EDSS (expanded disability status scale), 9-Hole Peg Test (performance index of upper extremity function), and Timed 25-foot Walk Test (performance index of lower extremity function) in the 0.5 mg group compared with the placebo group (hazard ratio: 0.95, 95% confidence interval 0.80 to 1.12).[1)]

[1)] Lublin, F., et al.: Lancet 2016; 387: 1075-1084

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