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*This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.*

## Revision of Precautions Fingolimod hydrochloride

September 15, 2015

### **Non-proprietary name**

Fingolimod hydrochloride

### **Safety measure**

Precautions should be revised in the package insert.

In the Clinically significant adverse reaction subsection of the Adverse Reaction section, the following text should be added (underlined parts are revised):

Progressive multifocal leukoencephalopathy (PML):

Progressive multifocal leukoencephalopathy (PML) may occur. Patients should be carefully monitored during and after treatment with this drug. If symptoms such as disturbed consciousness, cognitive disorder, symptoms of paralysis (hemiplegia or quadriplegia), or speech and language disorder are observed, imaging diagnostics with MRI and cerebrospinal fluid tests should be performed. In addition, administration of this drug should be discontinued, and appropriate measures should be adopted.