

## Update in Neurology

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One important step in modern treatment of multiple sclerosis is recent FDA approval for oral immunomodulatory therapy in the last months of 2010.

Multiple Sclerosis (MS), an autoimmune disease of the central nervous system, that is chronic and progressive, affects more than 2.1 million worldwide. The most common form of the disease is relapsing-remitting, characterized by exacerbations interspersed with periods of disease remission. The onset is frequent in early adulthood between the ages of 20 and 50 and affects women twice as men.

Fingolimod (Gilenya) 0.5 mg daily, is the first approved oral treatment indicated for relapsing-remitting form of MS. This new treatment option offers a significant efficacy and is a welcome alternative to frequent injections of interferon or glatiramer acetate for individuals living with this chronic disease.

Fingolimod is the first in a new class of drugs called sphingosine 1-phosphate receptor (S1PR) modulators. Through a novel mechanism of action, Gilenya reduces the frequency of MS relapses. Its approval was based on the largest clinical trial program ever submitted to date to the FDA for a new MS drug and in-

cluded combined data from clinical studies showing significant efficacy in reducing relapses, the risk of disability progression, and the number of brain lesions detected by magnetic resonance imaging (MRI), a measure of disease activity.

The FDA regulatory application included data showing Gilenya 0.5 mg reduced relapses by 52% ( $p < 0.001$ ) at one year compared with interferon beta-1a IM (Avonex), one of the most commonly prescribed treatment for MS. Fingolimod also reduced disease activity as measured by the number of new and newly enlarged T2 lesions on MRI scans compared to interferon beta-1a IM at one year (1).

Fingolimod has a well-studied safety and tolerability profile. It may cause serious side-effects such as bradycardia or bradyarrhythmia, infections, macular edema, breathing and liver problems. The most common side effects were: headache, flu, diarrhea, back pain, cough.

Gilenya has been approved in the United States with a Risk Evaluation and Mitigation Strategy (REMS) to inform patients and healthcare providers on the safe use and serious risk of Gilenya in treating relapsing forms of MS. The approved REMS include a medication guide for patients, and a letter and safety information guide for healthcare providers.

## REFERENCES

1. Cohen JA, Barkhof F, Comi G, et al. – Oral Fingolimod or Intramuscular Interferon for Relapsing Multiple Sclerosis, *N Engl J Med* 2010;362:402-15.

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