Generic Name:
Fingolimod
Trade Name:
Gilenya
Company:
Novartis
Notes:

FDA approved fingolimod to treat relapsing multiple sclerosis (MS) in children and adolescents aged 10 years and older. This is the first FDA approval of a drug to treat MS in pediatric patients.

Fingolimod was first approved by FDA in 2010 to treat adults with relapsing MS.

Approval was based on a clinical trial evaluating the effectiveness of fingolimod in treating 214 patients aged 10 to 17 with MS. The trial compared fingolimod with another MS drug, interferon beta-1a.

In the study, 86% of patients receiving fingolimod remained relapse-free after 24 months of treatment, compared with 46% of those receiving interferon beta-1a.

Adverse effects of fingolimod in pediatric trial participants were similar to those seen in adults. The most common adverse effects were headache, liver enzyme elevation, diarrhea, cough, flu, sinusitis, back pain, abdominal pain, and pain in extremities.

Fingolimod must be dispensed with a patient Medication Guide explaining serious risks, including slowing of the heart rate, especially after the first dose. Fingolimod may increase the risk of serious infections. Patients should be monitored for infection during treatment and for 2 months after treatment is discontinued.

Progressive multifocal leukoencephalopathy (PML), a rare brain infection that usually leads to death or severe disability, has been reported in patients being treated with fingolimod. PML cases usually occur in patients with weakened immune systems.

Fingolimod can cause vision problems and may increase the risk posterior reversible encephalopathy syndrome. Other serious risks include respiratory problems, liver injury, increased blood pressure, and skin cancer.

Fingolimod can cause harm to a developing fetus; women of child-bearing age should be advised of the potential risk to the fetus and to use effective contraception.

Medication Monitor Categories:
Supplemental Approvals