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Use of MS drug expanded to include children

May 14 2018

(HealthDay)—The U.S. Food and Drug Administration has expanded its approval of the multiple sclerosis drug Gilenya (fingolimod) to include children aged 10 and older.

It's the first multiple sclerosis drug approved for children, the agency said in a news release. The drug was approved in 2010 to treat adults with relapsing MS.

Multiple sclerosis is a chronic central nervous system disease that disrupts communication between the brain and other parts of the body. It occurs more frequently in women than men. The inflammatory autoimmune disease leads to a progressive decline in motor function. Initial symptoms usually emerge between ages 20 and 40, the FDA said.

But an estimated 8,000 to 10,000 children and teens in the United States have MS, and up to 5 percent of people have symptom onset before age 18, the agency said.

In clinical testing among more than 200 children ages 10 to 17, 86 percent of trial participants given Gilenya were symptom free after 24 months, compared to 46 percent of patients given the drug interferon beta-1a.

Gilenya's side effects in children were similar to those seen in adults, including headache, elevated liver enzymes, diarrhea, cough, sinusitis, and pain in the back, abdomen, arms and legs, the FDA said.

More severe risks include slowed heart rate, serious infections, vision problems, respiratory problems, liver injury and high blood pressure. The drug shouldn't be taken by women who are pregnant or expecting to become pregnant because it can harm a developing fetus.

Gilenya is produced by the Swiss drugmaker Novartis.

More information: The FDA has more about this approval.