

Gilenya[®] (fingolimod) – New warning

- On November 20, 2018, the [FDA announced](#) that a warning about the potential risk of severe increase in disability when [Gilenya \(fingolimod\)](#) therapy is stopped will be added to the Gilenya drug label and patient Medication Guide.
 - Gilenya is approved for the treatment of relapsing forms of multiple sclerosis (MS) in patients 10 years of age and older.
- MS can become much worse than before Gilenya was started or while it was being taken. This MS worsening is rare but can result in permanent disability.
- Health care professionals should inform patients before starting Gilenya treatment about the potential risk of severe increase in disability after stopping therapy. When Gilenya is stopped, patients should be carefully observed for evidence of an exacerbation of their MS and treated appropriately. Patients should be advised to seek immediate medical attention if they experience new or worsened symptoms of MS after Gilenya is stopped.
- Patients should contact their health care professional immediately if they experience new or worsened symptoms of MS after Gilenya treatment is stopped. These symptoms vary and include new or worsened weakness, increased trouble using arms or legs, or changes in thinking, eyesight or balance.
- Gilenya treatment may have to be stopped for reasons such as adverse drug reactions, planned or unplanned pregnancy, or because the medicine is not working. However, patients should not stop taking Gilenya without first talking to their prescribers.
- The safety update is based on the identification of 35 cases of severely increased disability accompanied by the presence of multiple new gadolinium-enhancing lesions on magnetic resonance imaging (MRI) following the discontinuation of Gilenya. These cases were reported in the FDA Adverse Event Reporting System database and the medical literature from September 2010 through February 2018.
 - Twenty-nine cases described symptoms of severe increase in disability beginning less than 12 weeks after Gilenya was discontinued, and 6 cases described symptoms beginning between 12 and 24 weeks after Gilenya was discontinued.
 - Diagnosis was based on MRI findings of multiple new gadolinium-enhancing lesions in the brain beyond baseline, and severe neurological symptoms based on clinical judgment or Expanded Disability Status Scale (EDSS) score worsening of any magnitude.
 - The most common reason for discontinuing Gilenya was that patients intended to become pregnant or had become pregnant. Other reasons for discontinuation included lack of efficacy, lymphopenia, infections, or cancer.
 - Patient outcomes after the severe increase in disability following Gilenya discontinuation varied. Of the 31 patients with adequately documented outcomes, 6 had a full recovery (reported as either a return to EDSS score reported while on Gilenya or “complete recovery”), 17 had a partial recovery, and 8 had permanent disability or no recovery.
- Treatments for increased disability varied; however, all 35 patients received corticosteroids as the initial treatment.

- The FDA has not determined the best approach to discontinuing treatment or the best way to treat a severe increase in disability if it occurs.



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