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

FDA is warning that when the multiple sclerosis (MS) medicine fingolimod is stopped, the disease can become much worse than before the medicine was started or while it was being taken. This MS worsening is rare but can result in permanent disability.

As a result, the agency has added a new warning about this risk to the prescribing information of the fingolimod drug label and patient Medication Guide.

Fingolimod, approved in the United States in 2010, is one of several medicines approved to treat relapsing MS.

Health professionals should inform patients before starting treatment about the potential risk of severe increase in disability after stopping the medication. When fingolimod 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 fingolimod is stopped. These symptoms vary and include new or worsened weakness, increased trouble using arms or legs, or changes in thinking, eyesight, or balance. 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 it without first talking to their prescribers.

In the 8 years since fingolimod was approved in September 2010, FDA identified 35 cases of severely increased disability accompanied by the presence of multiple new lesions on magnetic resonance imaging that occurred 2 to 24 weeks after fingolimod was stopped. Most patients experienced this worsening in the first 12 weeks after stopping. FDA's analyses included only reports submitted to FDA and those found in the medical literature, so the agency said there may be additional cases about which it us unaware.

The severe increase in disability in these patients was more severe than typical MS relapses, and in cases where baseline disability was known, appeared unrelated to the patients? prior disease state. Several patients who were able to walk without assistance prior to discontinuing fingolimod progressed to needing wheelchairs or becoming totally bedbound.

In patients experiencing worsening of disability after stopping fingolimod, recovery varied. Seventeen patients had partial recovery, 8 experienced permanent disability or no recovery, and 6 eventually returned to the level of disability they had before or during fingolimod treatment.

Medication Monitor Categories: