

November 21, 2018

COM-2018-024

Dear provider of healthcare services,

This communication intends to notify you that the United States Food and Drug Administration (FDA) is adding a new warning to the label of the multiple sclerosis (MS) medicine Gilenya™ (Fingolimog).

The FDA is warning that when Gilenya™ is stopped, the disease can become much worse than before the medicine was started or while it was being taken. Although this MS worsening is rare, it can result in permanent disability.

RECOMMENDATIONS FOR HEALTHCARE PROFESSIONALS
Inform your patients before starting treatment about the potential risk of severe increase in disability after stopping Gilenya™.
Carefully observe patients for evidence of an exacerbation of their MS and treat appropriately when Gilenya™ is stopped.
Advise patients to seek immediate medical attention if they experience new or worsened symptoms of MS after Gilenya™ is stopped.
Test for new or enhancing lesions by magnetic resonance imaging (MRI) if an increase in disability occurs and begin appropriate treatment as needed.
Encourage patients to read the patient Medication Guide they receive with their Gilenya™ prescriptions, which explains the benefits and risks of the medicine.

For more information regarding this and other safety communications, please visit the FDA website (www.fda.gov). To keep up to date with FDA Safety Communications, we recommend you subscribe to MedWatch Safety Alerts to receive these communications in a timely manner. You can easily subscribe to these alerts at <https://www.fda.gov/Safety/MedWatch/ucm228488.htm>.

On PharmPix we are compromised with the health and wellness of our insured. It is our priority to offer high quality services and to promote practices for health promotion and diseases prevention. If you have any doubt or wish to have more information regarding this document, you can call us to 787-522-5252, extension 138.

Regards,

Pharmacy Department

References:

- Gilenya (fingolimod): Drug Safety Communication - Severe Worsening of Multiple Sclerosis After Stopping the Medicine. US Food and Drug Administration. (11/20/2018). Available at: <https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm626264.htm>

