ProCare Rx

URGENT NOTICE

TYPE: DRUG SAFETY COMMUNICATION

Case of Rare Brain Infection PML Reported

Drug Name: **Tecfidera (dimethyl fumarate) by Biogen**

Audience: Neurology

Date: **11/26/2014**

ISSUE

FDA is warning that a patient with multiple sclerosis (MS) who was being treated with Tecfidera (dimethyl fumarate) developed a rare and serious brain infection called progressive multifocal leukoencephalopathy (PML), and later died. The patient who died was not taking any other drugs that affect the immune system or drugs that are thought to be associated with PML. As a result, information describing this case of PML is being added to the Tecfidera drug label.

PML is a rare and serious brain infection caused by the John Cunningham (JC) virus. The JC virus is a common virus that is harmless in most people but can cause PML in some patients who have weakened immune systems. See the *FDA Drug Safety Communication* for additional clinical information about this case.

BACKGROUND

Tecfidera is a drug used to treat relapsing forms of multiple sclerosis (MS), a brain and spinal cord disease in which patients experience multiple episodes of weakness, numbness, and other nervous system signs and symptoms that partially or completely resolve overs weeks or months. Patients may develop persistent symptoms and disability over time.

RECOMMENDATION Healthcare professionals should:

- Tell patients taking Tecfidera to contact you if they develop any symptoms that may be suggestive of progressive multifocal leukoencephalopathy (PML). Symptoms of PML are diverse, progress over days to weeks, and include the following: progressive weakness on one side of the body or clumsiness of limbs; disturbance of vision; and changes in thinking, memory and orientation, leading to confusion and personality changes. The progression of deficits can lead to severe disability or death.
- Stop Tecfidera immediately at the first sign or symptom suggestive of PML and perform an appropriate diagnostic evaluation.
- Monitor lymphocyte counts in Tecfidera-treated patients according to approved labeling.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: *www.fda.gov/MedWatch/report.htm*
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178