# Tysabri (natalizumab): Drug Safety Communication - New Risk Factor for Progressive Multifocal Leukoencephalopathy (PML)

U.S. Food & Drug Administration

**AUDIENCE**: Neurology, Gastroenterology

**ISSUE**: FDA notified healthcare profesisonals that testing positive for anti-JC virus (JCV) antibodies has been identified as a risk factor for progressive multifocal leukoencephalopathy (PML). PML is a rare but serious brain infection associated with use of Tysabri (natalizumab) for the treatment of multiple sclerosis (MS) or Crohn's disease.

A patient's anti-JCV antibody status may be determined using an anti-JCV antibody detection test that has been analytically and clinically validated, and has been ordered by a healthcare professional. The Stratify JCV Antibody ELISA test2 was cleared by FDA on January 20, 2012. Testing positive for anti-JCV antibodies means that a person has been exposed to JCV in the past.

**BACKGROUND**: Tysabri (natalizumab) is in a class of medications called immunomodulators. It works by stopping certain cells of the immune system from causing damage to the body. Tysabri is approved for the treatment of relapsing forms of multiple sclerosis since November 2004 and for the treatment of moderately to severely active Crohn's disease since January 2008.

**RECOMMENDATION**: The risks and benefits of continuing treatment with Tysabri should be carefully considered in patients who are found to be anti-JCV antibody positive and have one or more of the other known risk factors for PML. Patients with all three known risk factors have an estimated risk of PML of 11/1,000 users. See the Drug Safety Communication Data Summary section for additional information.

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 [1]
- Download form [2] 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

[01/20/2012 - Drug Safety Communication [3] - FDA]

[01/20/2012 - News Release [4] - FDA]

[09/2011 - Prescribing Information [5]]

Previous MedWatch Alerts:

[04/22/2011 [6]]
[02/05/2010 [6]]
[09/17/2009 [7]]
[08/25/2008 [8]]

SOURCE [9]

**Source URL (retrieved on *05/20/2013 - 4:33am*):**
http://www.mdtmag.com/news/2012/01/tysabri-natalizumab-drug-safety-communication-new-risk-factor-progressive-multifocal-leukoencephalopathy-pml

**Links:**
[1] http://www.fda.gov/MedWatch/report.htm
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
[3] http://www.fda.gov/Drugs/DrugSafety/ucm288186.htm
[4] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm288471.htm
[5] http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/125104s0658lbl.pdf
[6] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm199965.htm
[7] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm182667.htm
[8] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm110599.htm
[9] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm288602.htm