

Safety

Tysabri (natalizumab)

Audience: Neurologists, other healthcare professionals, patients

[Posted 08/25/2008] FDA informed healthcare professionals of two new cases of progressive multifocal leukoencephalopathy (PML) in European patients receiving Tysabri monotherapy for multiple sclerosis for more than one year. PML, which is usually fatal, is a known risk of Tysabri treatment, but previous cases in patients with multiple sclerosis were seen in combination with other immunomodulatory therapies. Approximately 39,000 patients have received treatment with Tysabri worldwide, with approximately 12,000 patients receiving treatment for a least one year. No new cases have been seen in the US, where about 7,500 patients have received the drug for greater than one year and approximately 3,300 patients have received the drug for at least one and one-half years. In the U.S., Tysabri is available only to patients with relapsing multiple sclerosis or Crohn's disease who are enrolled in the risk minimization plan called the TOUCH Prescribing Program. Under this program, every Tysabri-treated patient is closely monitored and followed for the occurrence of PML and other serious opportunistic infections. While the two patients who developed PML were on monotherapy, the FDA still believes that Tysabri monotherapy may confer a lower risk of PML than when Tysabri is used together with other immunomodulatory medications. Prescribing information for Tysabri will be revised to include information informing prescribers and patients that cases of PML have occurred in patients taking Tysabri as monotherapy. Healthcare professionals should continue to monitor patients for sign and symptoms of PML. Additionally, Tysabri should not be infused if PML is suspected.

[August 25, 2008 - [Information for Healthcare Professionals](#) - FDA]

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