

## Safety

### Natalizumab (marketed as Tysabri)

**Audience:** Neurological healthcare professionals, patients

[Posted 09/17/2009] FDA continues to receive reports of progressive multifocal leukoencephalopathy (PML) in patients receiving Tysabri. Tysabri was approved by the FDA for the treatment of relapsing forms of multiple sclerosis (MS) in November 2004 and for moderately to severely active Crohn's disease in January 2008. From July 2006, (when Tysabri marketing resumed) to September 8, 2009, 13 reported cases of Tysabri-related PML were confirmed worldwide in patients being treated for MS with Tysabri monotherapy. There have been no postmarketing reports of PML in patients treated with Tysabri for Crohn's disease. Less than 2% of Tysabri use in the U.S. has been in patients with Crohn's disease. Based on available data from the U.S. and outside of the U.S., the current rate of PML in patients who have received at least 24 infusions ranges from 0.4 to 1.3 per 1,000 patients.

The risk for developing PML appears to increase with the number of Tysabri infusions received. At this time, the FDA is not requiring changes regarding PML to the Tysabri prescribing information or to the Tysabri risk management plan, called the TOUCH Prescribing Program.

[09/16/2009 - [Information For Healthcare Professionals](#) - FDA]

Previous MedWatch Alert:

[[08/25/2008](#)]