Tysabri (natalizumab): Update of Healthcare Professional Information

U.S. Food & Drug Administration

[**UPDATED** Posted 04/22/2011] FDA has updated the Tysabri (natalizumab) Prescribing Information to give new information about the size of the risk of progressive multifocal leukoencephalopathy (PML), a rare but serious brain infection, associated with use of Tysabri for the treatment of multiple sclerosis (MS) and Crohn's disease. The update includes new safety information about patients who have taken other drugs that suppress the immune system, who may be at a higher risk for PML. Tysabri, in a class of medications called immunomodulators, has been approved by the FDA 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. The revised label includes a table summarizing rates of PML with Tysabri use according to the number of infusions (how long the drug is taken or duration of exposure) and information on a newly identified PML risk factor.

FDA notified healthcare professionals and patients that the risk of developing progressive multifocal leukoencephalopathy (PML) increases with the number of Tysabri infusions received. This new safety information, based on reports of 31 confirmed cases of PML received by the FDA as of January 21, 2010, will now be included in the Tysabri drug label and patient *Medication Guide*. Information about the occurrence of Immune Reconstitution Inflammatory Syndrome (IRIS) in patients who have developed PML and subsequently discontinued Tysabri has also been added to the drug label. IRIS is a rare condition characterized by a severe inflammatory response that can occur during or following immune system recovery, causing an unexpected decline in a patient’s condition after return of immune function.

Based on the available information, FDA believes that the clinical benefits of Tysabri continue to outweigh the potential risks. Revisions to the drug label and patient *Medication Guide*, with the continued use of the TOUCH Prescribing Program, are intended to maximize the safe use of Tysabri and the identification of new PML cases.

[04/22/2011 - Drug Safety Communication [1] - FDA]

[02/05/2010 - Drug Safety Communication [2] - FDA]

Previous MedWatch Alerts:
[09/17/2009 [3]]
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