

UPDATE



Natalizumab (Tysabri) – Posted on January 2014

Information for Healthcare Professionals

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12/2013: The US Food and Drug Administration (FDA) has approved a change to the prescription [label](#) for natalizumab (Tysabri) to include new information:

Under Boxed Warning

The boxed warning has changed to include the known risk factors for the development of progressive multifocal leukoencephalopathy (PML).

Natalizumab increases the risk of PML, an opportunistic viral infection of the brain that usually leads to death or severe disability. Risk factors for the development of PML include:

- duration of therapy
- prior use of immunosuppressants
- presence of anti-JCV antibodies (JCV ab)

These factors should be considered in the context of expected benefit when initiating and continuing treatment with natalizumab.

Under indications (1.1)

The indication no longer states that natalizumab is generally recommended for patients who have had inadequate response to or are unable to tolerate an alternate multiple sclerosis (MS) therapy:

Natalizumab is indicated as monotherapy for the treatment of patients with relapsing forms of MS. Because natalizumab increases the risk of PML, upon initiating and continuing treatment with this medication, physicians should consider whether the expected benefit of natalizumab is sufficient to offset this risk. See important information regarding the risk of PML with natalizumab.

Under Warnings and Precautions (5.1, 5.3, 5.4)

5.1. Progressive Multifocal Leukoencephalopathy

The label has been updated to reflect the US incidence of PML for both anti-JCV antibody positive and negative patients for up to 6 years of treatment, and continues to recommend monitoring for PML for at least 6 months after discontinuing treatment with natalizumab. In addition, language regarding seroconversion and serostatus change was also added to the label.

Table 1: Estimated US incidence of PML, stratified by risk factor

Anti-JC virus negative**	Natalizumab Exposure†	Anti-JC virus positive*	Anti-JC virus positive*
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