



Patient Information Sheet

Natalizumab (marketed as Tysabri)

What is Tysabri?

Tysabri is an intravenous (I.V.) medicine used to treat patients with relapsing forms of multiple sclerosis (MS) to reduce the number of relapses. A relapse is a time when new symptoms can appear and old symptoms come back or worsen. Relapses are followed by periods of time when no new symptoms occur (remission).

Tysabri is indicated for use as monotherapy, meaning it should not be used in combination with other immune system modifying drugs, and is for patients who have not responded adequately to, or cannot tolerate, other treatments for MS.

What are The Risks?

The following are the major potential risks and side effects of Tysabri therapy. However, this list is not complete.

Tysabri increases the chance of patients getting a rare brain infection that usually causes death or severe disability. This infection is called progressive multifocal leukoencephalopathy (PML). PML usually happens in people with weakened immune systems. Because of the risk of PML, Tysabri is available only through a special restricted distribution program.

Tysabri may cause severe allergic reactions. These severe reactions usually happen within 2 hours of the start of the Tysabri infusion. Symptoms of a severe allergic reaction include an itchy swelling on the skin (hives), dizziness, fever, rash, shaking, nausea, flushing, low blood pressure, trouble breathing, and chest pain. People who have these severe reactions with Tysabri must have their infusion stopped right away, be treated for the reaction, and should not be treated with Tysabri again.

The serious side effects with Tysabri include:

- serious infections, such as pneumonia
- severe or life threatening allergic reactions

Other side effects may include infections, such as in the urinary tract or upper respiratory tract, headache, tiredness, depression, joint pain, diarrhea, and stomach area pain.

What Should I Tell My Healthcare Professional?

Before being treated with Tysabri tell your healthcare professional if you:

- have any new or worsening medical problems (such as a new or sudden change in your thinking, eyesight, balance, or strength or other problems) that have lasted several days
- have a fever or infection (including shingles or any unusually long lasting infection)
- are pregnant, planning to become pregnant, or are breast-feeding

During or after treatment with Tysabri tell your healthcare professional if you:

- experience itching or any of the symptoms of an allergic reaction (listed under “risks”) after receiving Tysabri

Are There Any Interactions With Drugs or Foods?

Tell your healthcare professional about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Especially tell your health care professional if you take:

- corticosteroid medicines
- any other medicines to treat multiple sclerosis, such as Interferon beta-1a (Avonex, Rebif); Interferon beta-1b (Betaseron), or glatiramer acetate (Copaxone).

These medicines and Tysabri may interact causing side effects or affect how each other work.

