



Natalizumab Injection

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IMPORTANT WARNING:

[Posted 08/25/2008] FDA informed healthcare professionals of two new cases of progressive multifocal leukoencephalopathy (PML) in European patients receiving natalizumab (Tysabri) monotherapy for multiple sclerosis for more than one year. PML, which is usually fatal, is a known risk of natalizumab 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 natalizumab 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., natalizumab is available only to patients with relapsing multiple sclerosis or Chron's disease who are enrolled in the risk minimization plan called the TOUCH Prescribing Program. Under this program, every natalizumab-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 natalizumab monotherapy may confer a lower risk of PML than when natalizumab is used together with other immunomodulatory medications. Prescribing information for natalizumab will be revised to include information informing prescribers and patients that cases of PML have occurred in patients receiving natalizumab as monotherapy. Healthcare professionals should continue to monitor patients for sign and symptoms of PML. Additionally, natalizumab should not be infused if PML is suspected. For more information visit the FDA website at: <http://www.fda.gov/Safety/MedWatch> and <http://www.fda.gov/Drugs>.

IMPORTANT WARNING:

Using natalizumab injection with other medications that affect the immune system may increase the risk that you will develop progressive multifocal leukoencephalopathy (PML; a rare infection of the brain that cannot be treated, prevented, or cured and that usually causes death or severe disability). There is not enough information to tell whether using natalizumab injection alone also increases this risk.

Tell your doctor if you have or have ever had PML, an organ transplant, or another condition that affects your immune system such as human immunodeficiency virus (HIV), acquired immunodeficiency syndrome (AIDS), leukemia (cancer that causes too many blood cells to be produced and released into the bloodstream), or lymphoma (cancer that develops in the cells of the immune system). Also tell your doctor if you are taking any other medications that affect the immune system such as adalimumab (Humira); azathioprine (Imuran); cyclophosphamide (Cytoxan); cyclosporine (Neoral, Sandimmune); etanercept (Enbrel); glatiramer

(Copaxone); infliximab (Remicade); interferon beta (Avonex, Betaseron, Rebif); medications for cancer; mercaptopurine (Purinethol); methotrexate (Rheumatrex); mitoxantrone (Novantrone); oral steroids such as dexamethasone (Decadron, Dexone), methylprednisolone (Medrol), prednisolone, and prednisone (Deltasone); sirolimus (Rapamune); and tacrolimus (Prograf). Your doctor may tell you that you should not use natalizumab injection.

Talk to your doctor about the risks of using natalizumab injection.

You may need to have a magnetic resonance imaging scan (MRI; a scan that shows pictures of the inside of the body) before you begin treatment with natalizumab.

A program called the TOUCH program has been set up to help manage the risks of natalizumab treatment. You can only receive natalizumab injection if you are registered with the TOUCH program, if natalizumab is prescribed for you by a doctor who is registered with the program, and if you receive the medication at an infusion center that is registered with the program. Your doctor will give you more information about the program, will have you sign an enrollment form, and will answer any questions you have about the program and your treatment with natalizumab injection.

As part of the TOUCH program, your doctor or nurse will give you a copy of the Medication Guide before you begin treatment with natalizumab injection and before you receive each infusion. Read this information very carefully each time you receive it and ask your doctor or nurse if you have any questions.

Also as part of the TOUCH program, your doctor will need to see you every 3 months at the beginning of your treatment and then at least every 6 months to decide whether you should continue using natalizumab. You will also need to answer some questions before you receive each infusion to be sure that natalizumab is still right for you

Call your doctor immediately if you develop any new or worsening medical problems during your treatment. Be especially sure to call your doctor if you experience any changes in your thinking, balance, eyesight, or strength that last several days.

Tell all the doctors who treat you that you are using natalizumab injection.

Why is this medication prescribed?

Pending revision, the material in this section should be considered in light of more recently available information in the MedWatch notification at the beginning of this monograph.

Natalizumab is used to prevent episodes of symptoms and slow the worsening of disability in patients with relapsing forms (course of disease where symptoms flare up from time to time) of multiple sclerosis (MS; a disease in which the nerves do not function properly and people may experience weakness, numbness, loss of muscle coordination, and problems with vision, speech, and bladder control). Natalizumab is usually used by people who were not helped by other medications for MS or who cannot take these medications. Natalizumab is also used to treat and prevent episodes of symptoms in people who have Crohn's disease (a condition in which the body attacks the lining of the digestive tract, causing pain, diarrhea, weight loss, and fever) who have not been helped by other medications or who cannot take other medications. Natalizumab is in a class of medications called immunomodulators. It works by stopping certain cells of the immune system from reaching the brain and spinal cord and causing damage.

How should this medicine be used?

Natalizumab comes as a concentrated solution (liquid) to be diluted and injected slowly into a vein by a doctor or nurse. It is usually given once every 4 weeks in a registered infusion center. It will take about 1 hour for you to receive your entire dose of natalizumab.

Natalizumab may cause serious allergic reactions that are most likely to happen within 2 hours after the beginning of an infusion, but may happen at any time during your treatment. You will have to stay at the infusion center for 1 hour after your infusion is finished. A doctor or nurse will monitor you during this time to see if you are having a serious reaction to the medication. Tell your

doctor or nurse if you experience any unusual symptoms such as those listed in the SIDE EFFECTS section, especially if they occur within 2 hours after the start of your infusion.

Natalizumab controls the symptoms of MS, but does not cure the condition. Keep all appointments to receive natalizumab even if you feel well.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Pending revision, the material in this section should be considered in light of more recently available information in the MedWatch notification at the beginning of this monograph.

Before using natalizumab,

- tell your doctor and pharmacist if you are allergic to natalizumab or any other medications.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking. Be sure to mention the medications listed in the IMPORTANT WARNING section. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you have or have ever had any of the conditions listed in the IMPORTANT WARNING section. Before you receive each infusion of natalizumab, tell your doctor if you have a fever or any type of infection, including infections that last for a long time such as shingles (a rash that may occur from time to time in people who have had chickenpox in the past).
- tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while using natalizumab, call your doctor.
- do not have any vaccinations without talking to your doctor.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

If you miss an appointment to receive a natalizumab infusion, call your doctor as soon as possible.

What side effects can this medication cause?

Pending revision, the material in this section should be considered in light of more recently available information in the MedWatch notification at the beginning of this monograph.

Natalizumab may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- headache
- extreme tiredness
- joint pain or swelling
- pain in arms or legs
- swelling of the arms, hands, feet, ankles, or lower legs

- muscle cramps
- stomach pain
- diarrhea
- heartburn
- constipation
- gas
- weight gain or loss
- depression
- night sweats
- painful, irregular, or missed menstruation (period)
- swelling, redness, burning, or itching of the vagina
- white vaginal discharge
- frequent or painful urination
- sudden need to urinate right away
- difficulty controlling urination
- tooth pain
- cold sores

Some side effects can be serious. If you experience any of the following symptoms or those mentioned in the IMPORTANT WARNING section, call your doctor immediately:

- sore throat, fever, cough or other signs of infection
- rash
- hives
- itching
- difficulty breathing
- chest pain
- dizziness
- chills
- flushing
- yellowing of the skin or eyes
- nausea
- vomiting
- unusual darkening of the urine

Natalizumab injection may cause other side effects. Call your doctor if you have any unusual problems while using this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online [at <http://www.fda.gov/Safety/MedWatch>] or by phone [1-800-332-1088].

In case of emergency/overdose

In case of overdose, call your local poison control center at 1-800-222-1222. If the victim has collapsed or is not breathing, call local emergency services at 911.

What other information should I know?

Pending revision, the material in this section should be considered in light of more recently available information in the MedWatch notification at the beginning of this monograph.

Keep all appointments with your doctor.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Tysabri®

Last Revised - 03/01/2008