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Natalizumab Injection

pronounced as (na ta liz' you mab)

IMPORTANT WARNING:

Receiving natalizumab injection 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). The chance that you will develop PML during your treatment with natalizumab is higher if you have one or more of the following risk factors.

- You have received many doses of natalizumab, especially if you have received treatment for longer than 2 years.
- You have ever been treated with medications that weaken the immune system, including azathioprine (Azasan, Imuran), cyclophosphamide, methotrexate (Otrexup, Rasuvo, Trexall, Xatmep), mitoxantrone, and mycophenolate mofetil (CellCept).
- A blood test shows that you have been exposed to John Cunningham virus (JCV; a virus that many people are exposed to during childhood that usually causes no symptoms but may cause PML in people with weakened immune systems).

Your doctor will probably order a blood test before or during your treatment with natalizumab injection to see if you have been exposed to JCV. If the test shows that you have been exposed to JCV, you and your doctor may decide that you should not receive natalizumab injection, especially if you also have one or both of the other risk factors listed above. If the test does not show that you have been exposed to JCV, your doctor may repeat the test from time to time during your treatment with natalizumab injection. You should not be tested if you have had a plasma exchange (treatment in which the liquid part of the blood is removed from the body and replaced with other fluids) during the past 2 weeks because test results will not be accurate.

There are other factors that may also increase the risk that you will develop PML. 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 or if you have ever taken any other medications that affect the immune system such as adalimumab (Humira); cyclosporine (Gengraf, Neoral, Sandimmune); etanercept (Enbrel); glatiramer (Copaxone, Glatopa); infliximab (Remicade); interferon beta (Avonex,

Betaseron, Rebif); medications for cancer; mercaptopurine (Purinethol, Purixan); oral steroids such as dexamethasone, methylprednisolone (Depo-medrol, Medrol, Solu-medrol), prednisolone (Prelone), and prednisone (Rayos); sirolimus (Rapamune); and tacrolimus (Astagraf, Envarsus XR, Prograf). Your doctor may tell you that you should not receive natalizumab injection.

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. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm> [<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>]) or the manufacturer's website to obtain the Medication Guide.

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, and for 6 months after your final dose. Be especially sure to call your doctor if you experience any of the following symptoms: weakness on one side of the body that worsens over time; clumsiness of the arms or legs; changes in your thinking, memory, walking, balance, speech, eyesight, or strength that last several days; headaches; seizures; confusion; or personality changes.

If your treatment with natalizumab injection is stopped because you have PML, you may develop another condition called immune reconstitution inflammatory syndrome (IRIS; swelling and worsening of symptoms that may occur as the immune system begins to work again after certain medications that affect it are started or stopped), especially if you receive a treatment to remove natalizumab from your blood more quickly. Your doctor will watch you carefully for signs of IRIS and will treat these symptoms if they occur.

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

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

Why is this medication prescribed?

Natalizumab is used to prevent episodes of symptoms and slow the worsening of disability in adults who have relapsing forms 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), including:

- clinically isolated syndrome (CIS; first nerve symptom episode that lasts at least 24 hours),
- relapsing-remitting disease (course of disease where symptoms flare up from time to time),
- active secondary progressive disease (later stage of disease with continuous worsening of symptoms.)

Natalizumab is also used to treat and prevent episodes of symptoms in adults 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 monoclonal antibodies. It works by stopping certain cells of the immune system from reaching the brain and spinal cord or digestive tract 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 hives, rash, itching, difficulty swallowing or breathing, fever, dizziness, headache, chest pain, flushing, nausea, or chills, especially if they occur within 2 hours after the start of your infusion.

If you are receiving natalizumab injection to treat Crohn's disease, your symptoms should improve during the first few months of your treatment. Tell your doctor if your symptoms have not improved after 12 weeks of treatment. Your doctor may stop treating you with natalizumab injection.

Natalizumab may help control your symptoms but will not cure your condition. Keep all appointments to receive natalizumab injection 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?

Before receiving natalizumab injection,

- tell your doctor and pharmacist if you are allergic to natalizumab, any other medications, or any of the ingredients in natalizumab injection. Ask your doctor or pharmacist for a list of the ingredients.

- 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 ever received natalizumab injection before and 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 breastfeeding. If you become pregnant while receiving natalizumab injection, 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?

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

- headache
- extreme tiredness
- drowsiness
- joint pain or swelling
- pain in arms or legs
- back pain
- 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
- difficulty controlling urination
- tooth pain
- mouth sores
- rash
- dry skin
- itching

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

- sore throat, fever, cough, chills, flu like symptoms, stomach cramps, diarrhea, frequent or painful urination, sudden need to urinate right away, or other signs of infection
- yellowing of the skin or eyes, nausea, vomiting, extreme tiredness, loss of appetite, dark urine, right upper abdominal pain
- vision changes, eye redness, or pain
- unusual bleeding or bruising
- small, round, red or purple-colored spots on the skin
- heavy menstrual bleeding

Natalizumab injection may cause other side effects. Call your doctor if you have any unusual problems while receiving 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 (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor may order certain lab tests to check your body's response to natalizumab injection.

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[®]

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