

Natalizumab: Patient drug information

Brand Names: US: Tysabri

Warning

- A brain problem called progressive multifocal leukoencephalopathy (PML) has happened with this drug. It may cause disability or can be deadly. Tell your doctor right away if you have signs like confusion, memory problems, low mood (depression), change in the way you act, change in strength on one side is greater than the other, trouble speaking or thinking, change in balance, or change in eyesight.
- The risk of PML is raised if you have had a John Cunningham virus (JCV) infection. The risk is also raised if you take this drug for a long time (especially more than 2 years) and if you have taken drugs that can weaken your immune system. Tell your doctor if any of these apply to you. If you have questions, talk with your doctor.
- Watch for side effects while getting this drug and for 6 months after your last dose.

What is this drug used for?

- It is used to treat MS (multiple sclerosis). Multiple sclerosis (MS) is the most common immune-mediated inflammatory demyelinating disease of the central nervous system.
- It is used to treat Crohn's disease.

What do I need to tell my doctor BEFORE I take this drug?

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
- If you are allergic to mouse proteins.
- If you have had a brain infection called progressive multifocal leukoencephalopathy.
- If you are taking any drugs that suppress your immune system.

What are some things I need to know or do while I take this drug?

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Have blood work checked as you have been told by the doctor.

- Some people have had side effects within a few hours of the start of the infusion. Tell your doctor if you have any bad effects during this time.
- You may have more chance of getting an infection. Wash hands often. Stay away from people with infections, colds, or flu.
- Talk with your doctor before getting any vaccines. Use of some vaccines with this drug may either raise the chance of an infection or make the vaccine not work as well.

What are some side effects that I need to call my doctor about right away?

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of infection like fever, chills, very bad sore throat, ear or sinus pain, cough, more sputum or change in color of sputum, pain with passing urine, mouth sores, or wound that will not heal.
- Signs of a urinary tract infection (UTI) like blood in the urine, burning or pain when passing urine, feeling the need to pass urine often or right away, fever, lower stomach pain, or pelvic pain.
- Signs of liver problems like dark urine, feeling tired, not hungry, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.
- Thoughts of hurting yourself or suicide.
- Low mood (depression).
- Dizziness.
- Flushing.
- Shortness of breath.
- Chest pain or pressure or passing out.
- Vaginal itching or discharge.
- Period (menstrual) changes.
- Swelling in the arms or legs.
- Very bad and sometimes deadly infections of the brain or spinal cord caused by herpes viruses have happened with this drug. Call your doctor right away if you have a sudden fever, very bad headache, or feel confused.
- An eye problem caused by herpes viruses has happened with this drug. Sometimes this has been very bad and has led to loss of eyesight in some people. Call your doctor right away if you have a change in eyesight, eye pain, or eye redness.

•Low platelet counts have rarely happened with this drug. Low platelet counts can lead to bleeding that may be life-threatening. Call your doctor right away if you have any unexplained bruising or bleeding.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Headache.
- Upset stomach; stomach pain or diarrhea.
- Feeling tired or weak.
- Joint pain; back pain; muscle cramps.
- Signs of a common cold.

How is this drug best taken?

- It is given as an infusion into a vein over a period of time.