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2. Natalizumab

# Natalizumab

**Generic name:** natalizumab

**Brand name:** [Tysabri](#)

**Dosage form:** intravenous (infusion) injection

**Drug class:** [Selective immunosuppressants](#)

Medically reviewed by [Philip Thornton, DipPharm](#). Last updated on Mar 25, 2025.

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## What is natalizumab?

Natalizumab is a type of biological medication called a monoclonal antibody. It is used to treat a disease of the central nervous system called [multiple sclerosis](#) and an inflammatory bowel condition known as [Crohn's disease](#).

Natalizumab is an immunosuppressant that works by attaching itself to the surface of leukocytes, which are white blood cells that circulate in your blood and help you when you get injured or are ill. White blood cells are part of the immune system and levels of them tend to be higher in people with conditions such as multiple sclerosis and Crohn's disease.

Natalizumab is an integrin receptor antagonist that specifically binds to integrins, a type of protein found on the surface of white blood cells. This prevents the white blood cells from migrating from the blood stream into areas of inflamed tissue.

It's not known exactly how this helps people with multiple sclerosis and Crohn's disease, but it is thought that by stopping the migration of the white blood cells, natalizumab helps to prevent nerve damage and inflammation.

Natalizumab was approved by the US Food and Drug Administration (FDA) in 2004. No biosimilars of it have been approved. Biosimilars are highly similar versions of the drug that are designed to have the same effect on a person, but a biosimilar is not identical to the original version.

## What is natalizumab used for?

Natalizumab is a prescription medicine used to treat adults with:

- relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease. natalizumab increases the risk of PML. When starting and continuing treatment with natalizumab, it is important that you discuss with your doctor whether the expected benefit of natalizumab is enough to outweigh this risk. See "Important Information" below.
- moderate to severe Crohn's disease. Natalizumab is used:
  - to reduce signs and symptoms of Crohn's disease
  - in people who have not been helped enough by, or cannot use the usual Crohn's disease medicines and

medicines called tumor necrosis factor (TNF) inhibitors.

- It is not known if natalizumab is safe and effective in children under 18 years of age.

## Important information

- Natalizumab increases your chance (risk) of getting a rare brain infection that usually leads to death or severe disability. This infection is called progressive multifocal leukoencephalopathy (PML). If PML happens, it usually happens in people with weakened immune systems.
  - There is no known treatment, prevention, or cure for PML.
  - Your chance of getting PML may be higher if you are also being treated with other medicines that can weaken your immune system, including other treatments for multiple sclerosis and Crohn's disease. You should not take certain medicines that weaken your immune system at the same time you are taking natalizumab. Even if you use natalizumab alone to treat your multiple sclerosis or Crohn's disease, you can still get PML.
  - Your risk of getting PML is higher if you:
    - have been infected by the John Cunningham Virus (JCV). JCV is a common virus that is harmless in most people but can cause PML in people who have weakened immune systems, such as people taking natalizumab. Most people who are infected by JCV do not know it or do not have any symptoms. This infection usually happens in childhood. Before you start receiving natalizumab or during your treatment, your doctor may do a blood test to check if you have been infected by JCV.
    - have received natalizumab for a long time, especially longer than 2 years
    - have received certain medicines that can weaken your immune system before you start receiving natalizumab

Your risk of getting PML is greatest if you have all 3 risk factors listed above. There may be other risk factors for getting PML during natalizumab treatment that we do not know about yet. Your doctor should discuss the risks and benefits of natalizumab treatment with you before you decide to receive natalizumab. See "What are the side effects of natalizumab?" below.

- While you receive natalizumab, and for 6 months after you stop receiving natalizumab, it is important that you call your doctor right away if you have any new or worsening medical problems that have lasted several days.

These may be new or sudden and include problems with:

- thinking
- balance
- eyesight
- weakness on 1 side of your body
- strength
- using your arms and legs

Tell all your doctors that you are receiving natalizumab.

- Because of your risk of getting PML while you receive natalizumab, natalizumab is available only through a

restricted distribution program called the TOUCH Prescribing Program. To receive natalizumab, you must talk to your doctor and understand the risks and benefits of natalizumab and agree to follow all of the instructions in the TOUCH Prescribing Program.

- Natalizumab is only:
  - prescribed by doctors who are enrolled in the TOUCH Prescribing Program
  - given at an infusion center that is enrolled in the TOUCH Prescribing Program
  - given to people who are enrolled in the TOUCH Prescribing Program
- Before you receive natalizumab, your doctor will:
  - explain the TOUCH Prescribing Program to you
  - have you sign the TOUCH Prescriber and Patient Enrollment Form

## Who should not receive natalizumab?

Do not receive natalizumab if you:

- have PML
- are allergic to natalizumab or any of the ingredients in natalizumab. See below for a complete list of ingredients in natalizumab.

Talk to your doctor before receiving natalizumab if you have any of these conditions.

 [Natalizumab pregnancy and breastfeeding warnings](#) (more detail)

## What should I tell my doctor before receiving natalizumab?

Before you receive natalizumab, tell your doctor if you:

- have medical conditions that can weaken your immune system, including:
  - HIV infection or AIDS
  - leukemia or lymphoma
  - an organ transplant
  - other medical conditions that can weaken your immune system
- have any new or worsening medical problems that have lasted several days. These may be new or sudden and include problems with:
  - thinking
  - strength
  - eyesight
  - weakness on 1 side of your body
  - balance
  - using your arms and legs

- have had hives, itching or trouble breathing during or after receiving a dose of natalizumab
- have a fever or infection (including shingles or any unusually long lasting infection)

## How should I receive natalizumab?

natalizumab is given 1 time every 4 weeks through a needle placed in your vein (IV infusion).

Before each natalizumab dose you will be asked questions to make sure natalizumab is still right for you.

## Dosing information

- The recommended dose of natalizumab is 300 mg infused intravenously over one hour, every four weeks. Natalizumab should not be given as an intravenous push or bolus.
- See full prescribing information for further information about natalizumab dosing.

 [Detailed Natalizumab dosage information](#)

## What are the side effects of natalizumab?

Natalizumab may cause serious side effects, including:

- See "Important information" above.
- Herpes Infections. Natalizumab may increase your risk of getting an infection of the brain or the covering of your brain and spinal cord (encephalitis or meningitis) caused by herpes viruses that may lead to death. Call your doctor right away if you have sudden fever, severe headache, or if you feel confused after receiving natalizumab. Herpes infections of the eye, causing blindness in some patients, have also occurred. Call your doctor right away if you have changes in vision, eye redness, or eye pain.
- Liver damage. Symptoms of liver damage can include:
  - yellowing of the skin and eyes (jaundice)
  - unusual darkening of the urine
  - nausea
  - feeling tired or weak
  - vomiting

Call your doctor right away if you have symptoms of liver damage. Your doctor can do blood tests to check for liver damage.
- Allergic reactions, including serious allergic reactions. Symptoms of an allergic reaction can include:
  - hives
  - dizziness
  - nausea
  - itching
  - wheezing

- flushing of skin
- trouble breathing
- chills
- low blood pressure
- chest pain
- Rash

Serious allergic reactions usually happen within 2 hours of the start of your infusion, but they can happen at any time after you receive natalizumab.

Tell your doctor right away if you have any symptom of an allergic reaction, even if it happens after you leave the infusion center. You may need treatment if you are having an allergic reaction.

- Infections. Natalizumab may increase your chance of getting an unusual or serious infection because natalizumab can weaken your immune system. You have a higher risk of getting infections if you also take other medicines that can weaken your immune system.
- Low platelet counts. Natalizumab may cause the number of platelets in your blood to be reduced. Call your healthcare provider if you have any of the following symptoms:
  - easy bruising
  - heavier menstrual periods than are normal
  - bleeding from your gums or nose that is new or takes longer than usual to stop
  - bleeding from a cut that is hard to stop
  - small scattered red spots on your skin that are red, pink, or purple

The most common side effects of natalizumab include:

- headache
- lung infection
- vaginitis
- stomach area pain
- feeling tired
- depression
- rash
- urinary tract infection
- pain in your arm and legs
- nose and throat infections
- joint pain
- diarrhea
- nausea

Tell your doctor about any side effect that bothers you or that does not go away.

These are not all the possible side effects of natalizumab. Ask your doctor for more information.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

 [Natalizumab side effects](#) (more detail)

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## Interactions

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.

Especially tell your doctor if you take medicines that can weaken your immune system, such as 6-mercaptopurine, azathioprine, cyclosporine, methotrexate, or TNF-alpha inhibitors and corticosteroids. Ask your doctor if you are not

sure.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

 [Natalizumab drug interactions](#) (more detail)

## Does natalizumab interact with my other drugs?

Enter medications to view a detailed interaction report using our [Drug Interaction Checker](#).

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## Pregnancy and breastfeeding

Tell your doctor if you are pregnant or plan to become pregnant. Natalizumab may cause low platelets, and in some cases also low red blood cells (anemia), in your newborn baby if you take natalizumab while you are pregnant. It is not known if natalizumab can cause birth defects.

Tell your doctor if you are breastfeeding or plan to breastfeed. Natalizumab can pass into your breast milk. It is not known if the natalizumab that passes into your breast milk can harm your baby. Talk to your doctor about the best way to feed your baby while you receive natalizumab.

## Storage

- Natalizumab single-dose vials must be refrigerated between 2°C to 8°C (36°F to 46°F).
- Do not use beyond the expiration date stamped on the carton and vial label.
- Do not shake or freeze.
- Protect from light.
- Store diluted natalizumab solution refrigerated at 2°C to 8°C (36°F to 46°F).
- Natalizumab solution must be administered within 8 hours of being prepared.

## What are the ingredients in natalizumab?

**Active ingredient:** natalizumab

**Inactive Ingredients:** sodium chloride, sodium phosphate, monobasic, monohydrate; sodium phosphate, dibasic, heptahydrate; polysorbate 80, and water for injection

Natalizumab is manufactured under the name Tysabri by Biogen Inc.; Cambridge, MA 02142 USA.

## Natalizumab Biosimilars



Biosimilar and interchangeable products are biological products that are highly similar to and have no clinically meaningful differences from the reference product.

## Reference products

These are biological products that have already been approved by the FDA, against which biosimilar products are compared. There is 1 for natalizumab.

### Tysabri (natalizumab) - Biogen Inc.



Formulation type	Strength
Single-Dose Vial	300 mg/15 mL (20 mg/mL)

View [Tysabri](#) information in detail.

## Tysabri biosimilar products

Biosimilar products can only be dispensed in place of the **reference product** if the healthcare provider specifically prescribes the biosimilar product by name.

Pharmacy laws for biosimilar prescribing may vary by state

### Tyruko (natalizumab-sztn) - Sandoz Inc.



## Popular FAQ

Does Tysabri suppress the immune system?



How long can you take Tysabri for?



Is Tysabri a form of chemotherapy?



Does Tysabri cause cancer?



## More FAQ

- [What biosimilars have been approved in the United States?](#)
- [How to prevent hair loss from Tysabri \(natalizumab\)?](#)

[View more FAQ...](#)

## References

1. [National Library of Medicine Tysabri Product Label](#)
2. [Babaesfahani A, Khanna NR, Kuns B. Natalizumab. \[Updated 2021 Jul 13\]. In: StatPearls \[Internet\]. Treasure Island \(FL\): StatPearls](#)

## More about natalizumab

- [Check interactions](#)
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- [Drug class: selective immunosuppressants](#)
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## Patient resources

- [Natalizumab-sztn advanced reading](#)

## Other brands

[Tysabri](#), [Tyruko](#)

## Professional resources

- [Natalizumab monograph](#)

## Other brands

[Tysabri](#)

## Related treatment guides

- [Crohn's Disease, Maintenance](#)
- [Multiple Sclerosis](#)

## Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

[Medical Disclaimer](#)

### DRUG STATUS

**Availability**

**Rx** Prescription only


**Pregnancy & Lactation**

 Risk data available

**CSA Schedule\***

**N/A** Not a controlled drug

**Approval History**

 Drug history at FDA



## User Reviews & Ratings

7.7 / 10

[102 Reviews](#)

## Images

[Tysabri \(natalizumab\) 300 mg/15 mL injection for intravenous infusion](#)

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