MEDICATION GUIDE

TYSABRI® (tie-SA-bree)
(natalizumab)
injection, for intravenous use

Read this Medication Guide before you start receiving TYSABRI and before you receive each dose. There may be new information. This Medication Guide does not take the place of talking to your doctor about your medical condition or your treatment.

What is the most important information I should know about TYSABRI?

- **TYSABRI 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 (MS) and Crohn's disease (CD). You should not take certain medicines that weaken your immune system at the same time you are taking TYSABRI. Even if you use TYSABRI alone to treat your MS or CD, 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 TYSABRI. 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 TYSABRI or during your treatment, your doctor may do a blood test to check if you have been infected by JCV.
    - have received TYSABRI for a long time, especially longer than 2 years
    - have received certain medicines that can weaken your immune system before you start receiving TYSABRI

    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 TYSABRI treatment that we do not know about yet. Your doctor should discuss the risks and benefits of TYSABRI treatment with you before you decide to receive TYSABRI. See "What are the possible side effects of TYSABRI?"
  - **While you receive TYSABRI, and for 6 months after you stop receiving TYSABRI, 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 TYSABRI.

- **Because of your risk of getting PML while you receive TYSABRI, TYSABRI is available only through a restricted distribution program called the TOUCH® Prescribing Program**. To receive TYSABRI, you must talk to your doctor and understand the risks and benefits of TYSABRI and agree to follow all of the instructions in the TOUCH® Prescribing Program.
  - **TYSABRI is only:**
    - prescribed by doctors who are enrolled in the TOUCH® Prescribing Program
    - given by an infusion nurse from 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 TYSABRI, your doctor will:**
    - explain the TOUCH® Prescribing Program to you
    - have you sign the TOUCH® Patient Enrollment Form

What is TYSABRI?

TYSABRI is a prescription medicine used to treat adults with:

- relapsing forms of Multiple Sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease. TYSABRI increases the risk of PML. When starting and continuing treatment with TYSABRI, it is important that you discuss with your doctor whether the expected benefit of TYSABRI is enough to outweigh this risk. See "**What is the most important information I should know about TYSABRI?**"
- moderate to severe Crohn's disease (CD). TYSABRI is used:
  - to reduce signs and symptoms of CD
  - in people who have not been helped enough by, or cannot use the usual CD medicines and medicines called tumor necrosis factor (TNF) inhibitors.
- It is not known if TYSABRI is safe and effective in children under 18 years of age.

Who should not receive TYSABRI?

Do not receive TYSABRI if you:

- have PML
- are allergic to natalizumab or any of the ingredients in TYSABRI. See the end of this Medication Guide for a complete list of ingredients in TYSABRI.

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

What should I tell my doctor before receiving each dose of TYSABRI?

Before you receive TYSABRI, 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
  - eyesight
  - balance
  - strength
  - weakness on 1 side of your body
  - using your arms and legs
- have had hives, itching or trouble breathing during or after receiving a dose of TYSABRI
- have a fever or infection (including shingles or any unusually long lasting infection)
- are pregnant or plan to become pregnant. TYSABRI may cause low platelets (thrombocytopenia) and low red blood cells (anemia) in your newborn baby if you take TYSABRI while you are pregnant. It is not known if TYSABRI can cause birth defects.
- are breastfeeding or plan to breastfeed. TYSABRI can pass into your breast milk. It is not known if the TYSABRI 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 TYSABRI.

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. 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.

How should I receive TYSABRI?

- TYSABRI is given 1 time every 4 weeks through a needle placed in your vein (IV infusion). Each infusion will last about 1 hour.
- Before each TYSABRI dose you will be asked questions to make sure TYSABRI is still right for you.

What are the possible side effects of TYSABRI?

TYSABRI may cause serious side effects, including:

- **See "What is the most important information I should know about TYSABRI?"**
- **Herpes Infections.** TYSABRI 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 TYSABRI. 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)
  - nausea
  - vomiting
  - unusual darkening of the urine
  - feeling tired or weak

  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
  - itching
  - trouble breathing
  - chest pain
  - dizziness
  - wheezing
  - chills
  - rash
  - nausea
  - flushing of skin
  - low blood pressure

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

  Tell your doctor right away if you have any symptom of an allergic reaction, even if it happens after your infusion. You may need treatment if you are having an allergic reaction.
- **Infections.** TYSABRI may increase your chance of getting an unusual or serious infection because TYSABRI 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.** TYSABRI 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 TYSABRI include:

- headache
- feeling tired
- urinary tract infection
- joint pain

- lung infection
- depression
- pain in your arm and legs
- diarrhea
- vaginitis
- rash
- nose and throat infections
- nausea
- stomach area pain

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 TYSABRI. 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.

General information about the safe and effective use of TYSABRI.
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.

This Medication Guide summarizes the most important information about TYSABRI. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about TYSABRI that is written for healthcare professionals.

For more information, go to www.TYSABRI.com or call 1-800-456-2255.

What are the ingredients in TYSABRI?
Active ingredient: natalizumab
Inactive Ingredients: sodium chloride, sodium phosphate, monobasic, monohydrate; sodium phosphate, dibasic, heptahydrate; polysorbate 80, and water for injection
Manufactured by: Biogen Inc.; Cambridge, MA 02142 USA

This Medication Guide has been approved by the U.S. Food and Drug Administration. Revised 3/2025