

MEDICATION GUIDE

TYSABRI® (tie-SA-bree) (natalizumab)

Read the Medication Guide given to you before you start **TYSABRI®** and before each infusion. 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. Ask your doctor or nurse if you have any questions.

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

- **TYSABRI® increases your chance of getting a rare brain infection that usually causes death or severe disability. This infection is called progressive multifocal leukoencephalopathy (PML).** PML usually happens in people with weakened immune systems.
- No one can predict who will get PML.
- 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 MS treatments.
- Even if you use **TYSABRI®** alone to treat your MS, it is not known if your chance of getting PML will be lower. It is also not known if treatment for a long period of time with **TYSABRI®** can increase your chance of getting PML.
- **TYSABRI®** is available only through a restricted distribution program called the **TOUCH™** Prescribing Program. In order to receive **TYSABRI®**, you must talk to your doctor and understand the benefits and risks of **TYSABRI®** and agree to all of the instructions in the **TOUCH™** Prescribing Program.

- If you take TYSABRI[®], it is important that you call your doctor right away if you get any new or worsening medical problems (such as a new or sudden change in your thinking, eyesight, balance, or strength or other problems) that have lasted over several days. Tell all of your doctors that you are getting treatment with TYSABRI[®].

Also, see “**What are the possible side effects with TYSABRI[®]?**” for other serious side effects with TYSABRI[®].

What is TYSABRI[®]?

TYSABRI[®] is a prescription medicine approved for patients with relapsing forms of MS to:

- slow the worsening of disability that is common in patients with MS and,
- decrease the number of flare-ups (relapses)
- Because of the chance of getting PML, TYSABRI[®] is generally recommended for patients that have not been helped enough by, or cannot tolerate other treatments for MS.
- TYSABRI[®] does not cure MS.
- TYSABRI[®] has not been studied for use longer than 2 years. Also, TYSABRI[®] has not been studied in patients with chronic progressive MS, or in children. It is not known if patients older than 65 years have a different response to TYSABRI[®].

TYSABRI[®] is only:

- prescribed by doctors who are enrolled in the TOUCH[™] Prescribing Program
- infused at an infusion center that is enrolled in the TOUCH[™] Prescribing Program
- given to patients who are enrolled in the TOUCH[™] Prescribing Program

Who should not receive TYSABRI[®]?

Do not receive TYSABRI® if you:

- have PML
- are allergic to TYSABRI®

TYSABRI is not recommended if you:

- have a medical condition that can weaken your immune system such as HIV infection or AIDS, leukemia or lymphoma, or an organ transplant, and others.
- are taking medicines that can weaken your immune system. Talk with your doctor about all of the medicines you take or have taken.

If you have questions about any of the above, talk to your doctor.

What should I tell my doctor and nurse before receiving each infusion of TYSABRI®?

Tell your doctor and nurse about all of your medical conditions. Tell them if you:

- have any new or worsening medical problems (such as a new or sudden change in your thinking, eyesight, balance, or strength or other problems) that have lasted several days
- have had hives, itching or trouble breathing during or after an infusion of TYSABRI®
- have a fever or infection (including shingles or any unusually long lasting infection)
- are pregnant or plan to become pregnant
- are breastfeeding

Tell your doctor and nurse about all of the medicines you are taking, including prescription and non-prescription medicines, vitamins and herbal supplements.

- Know the medicines you take. Keep a list of them with you to show your doctor and nurse. The nurse may ask to see this list before every TYSABRI[®] infusion.

How do I receive TYSABRI[®]?

- TYSABRI[®] is given once every four weeks through a needle placed in a vein (IV infusion).
- You must follow all the instructions of the TOUCH[™] Prescribing Program. Before you can begin to receive TYSABRI[®], your doctor or nurse will:
 - explain the TOUCH[™] Prescribing Program to you
 - have you sign the TOUCH[™] Prescriber/Patient Enrollment Form
- Before every TYSABRI[®] infusion you will be asked a series of questions to confirm that TYSABRI[®] is still right for you.
- Call your doctor who prescribes TYSABRI[®] right away to report any medical problems that keep getting worse and last several days.

What are the possible side effects of TYSABRI[®]?

TYSABRI[®] increases your chance of getting a rare brain infection that usually causes death or severe disability. This infection is called progressive multifocal leukoencephalopathy (PML). PML usually happens in people with weakened immune systems. (see “What is the most important information I should know about TYSABRI[®]?”)

Other serious side effects with TYSABRI[®] include:

- Allergic reactions including serious allergic reactions. Symptoms can include:
 - hives
 - itching
 - trouble breathing
 - chest pain
 - dizziness
 - chills
 - rash
 - nausea
 - flushing of skin
 - low blood pressure

- Serious allergic reactions usually happen within 2 hours of the start of the infusion, but they can happen at any time after receiving TYSABRI®.
- Tell your doctor or nurse 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.** TYSABRI® may increase your chance of getting an unusual or serious infection because TYSABRI® can affect your immune system.

Other side effects with TYSABRI® include:

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

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

These are not all the side effects with TYSABRI®. Ask your doctor for more information.

General information about the safe and effective use of TYSABRI®

This Medication Guide provides a summary of the most important information about TYSABRI®. If you would like more information or have any questions, talk with your doctor or nurse. You can ask your doctor or nurse for information about TYSABRI that is written for healthcare professionals. You can also call 1-800-456-2255 or visit www.TYSABRI.com.

What are the ingredients in TYSABRI®?

Each dose of TYSABRI[®] contains natalizumab; sodium chloride; sodium phosphate, monobasic, monohydrate; sodium phosphate, dibasic, heptahydrate; polysorbate 80; and water for injection.

Manufactured by Biogen Idec Inc.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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