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).** If PML happens, it 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 treatments for Multiple Sclerosis (MS) and Crohn's disease (CD). You should not take certain medicines that weaken the 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 chance of getting PML increases:
    - with a longer period of TYSABRI treatment
    - if you have received medicines that can weaken your immune system prior to starting TYSABRI.

- 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.

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:

1. **Adult patients with relapsing forms of Multiple Sclerosis (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 another treatment for MS.

2. **Adult patients with moderate to severe Crohn's disease:**

    - To reduce signs and symptoms of Crohn's disease
    - In patients who have not been helped enough by, or cannot tolerate usual Crohn's disease medicines and medicines called tumor necrosis factor (TNF) inhibitors.

- TYSABRI does not cure MS or Crohn's disease.
- TYSABRI has not been studied for use longer than 2 years.
- TYSABRI has not been studied in patients with chronic progressive MS.
- It is not known if patients older than 65 years have a different response to TYSABRI.
- TYSABRI is not approved for use in patients under age 18.

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 or plan to breastfeed. TYSABRI can pass into your milk.** It is not known if the TYSABRI that passes into breast milk can harm your baby.
- 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). If PML happens, it 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:

- **Infections.** TYSABRI may increase your chance of getting an unusual or serious infection because TYSABRI can weaken your immune system.

- Allergic reactions including serious allergic reactions**.** Symptoms 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 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.

- **Liver damage.** TYSABRI may cause liver damage. Symptoms can include**:**
    - yellowing of the skin and eyes (jaundice)
    - nausea
    - vomiting
    - unusual darkening of the urine
    - feeling tired or weak

    Blood tests can be done to check for liver damage. Call your doctor right away if you have symptoms of liver damage.

Other side effects with TYSABRI include:

- headache
- urinary tract infection
- lung infection
- pain in your arm and legs
- vaginitis
- nose and throat infections
- 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**.

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

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 Idec Inc.

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