

Important Safety Information

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. Your chances may be higher if you are also being treated with medicines that weaken your immune system, including other MS treatments. If you use TYSABRI alone to treat your MS, you can still get PML. It is not known if the length of time on treatment with TYSABRI increases your chance of getting PML. There is no known treatment, prevention, or cure for PML. If you take TYSABRI, it is important to call your doctor right away 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 over several days. Tell all of your doctors that you are getting treatment with TYSABRI.

Because of the chance for PML, TYSABRI is generally recommended for patients that have not been helped enough by, or cannot tolerate another treatment for MS. TYSABRI is available only through the TOUCH® Prescribing Program, which is a restricted distribution program. Only prescribers, patients, and infusion centers enrolled in the TOUCH Prescribing Program can prescribe, receive, and infuse TYSABRI. Before you take TYSABRI, you and your doctor must enroll in the TOUCH Prescribing Program and agree to the program requirements. Plan to see your doctor 3 months after the first infusion, 6 months after the first infusion, and at least as frequently as 6 months thereafter. TYSABRI does not cure MS and has not been studied longer than two years or in patients with chronic progressive MS. TYSABRI is not approved for use in patients under age 18.

You should not receive TYSABRI if you have PML or are allergic to TYSABRI or any of its ingredients.

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, organ transplant, or others, or if you are taking medicines that weaken your immune system. Talk with your doctor about all of the medicines you take or have taken. TYSABRI may increase your chance of getting an unusual or serious infection. You should not take TYSABRI if you are pregnant, trying to become pregnant, or nursing.

TYSABRI may cause liver damage. Symptoms of liver damage can include yellowing of the skin and eyes (jaundice), unusual darkening of urine, nausea, feeling tired or weak, or vomiting. Blood tests can be done to check for liver damage. Call your doctor right away if you experience any symptoms of liver damage.

Other serious side effects with TYSABRI include allergic reactions (e.g., hives, itching, trouble breathing, chest pain, dizziness, wheezing, chills, rash, nausea, flushing of skin, low blood pressure), including serious allergic reactions (e.g., anaphylaxis) and infections. Serious allergic reactions usually happen within 2 hours of the start of the infusion, but can happen any time after receiving TYSABRI. Tell your doctor or nurse right away if you have any symptom of an allergic reaction. You may need treatment if you are having an allergic reaction. TYSABRI may increase your chance of getting an unusual or serious infection, because it can affect your immune system.

Common side effects include headache, urinary tract infection, lung infection, pain in your arms and legs, vaginitis, stomach area pain, feeling tired, joint pain, depression, diarrhea, and rash. Tell your doctor about any side effect that bothers you or does not go away.