

Information Sheet



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TYSABRI (Natalizumab)

Who is prescribed Tysabri?

Tysabri is given to patients with highly active forms of relapsing-remitting MS or those who have failed on other disease-modifying therapies. 'Highly active' is defined as two or more disabling relapses in a year and the presence of more lesions on the brain in an MRI scan.

How is Tysabri different from other therapies?

A drug for people with relapsing-remitting MS, Tysabri works in a different way from other disease-modifying drugs. It prevents the immune cells leaving the bloodstream and entering areas of inflammation (e.g. MS lesions in the brain and spinal cord). In clinical trials, Tysabri approximately halved the progression of the disabling effects of MS and also decreased the number of MS attacks by two-thirds.

How and where is Tysabri administered?

Tysabri is administered by intravenous (IV) infusion in a hospital or clinic setting once every four weeks.

How long does an infusion take?

An infusion can take approximately one hour, and for one hour afterwards patients will be monitored for any adverse reactions.

What do I do if I miss an infusion?

You should reschedule your next infusion as soon as possible

What side effects are associated with Tysabri?

The most common side effects of Tysabri include: itchy rash (hives); urinary tract infection; sore throat and runny or blocked up nose; shivering; headache; dizziness; feeling sick (nausea); being sick (vomiting); joint pain; fever and tiredness.

The most serious, but rare, side effect of Tysabri is the risk of developing progressive multifocal leukoencephalopathy (PML), a potentially fatal disease caused by a rare infection in the brain. The symptoms of PML may be similar to that of an MS relapse. Patients are continuously monitored during their treatment for any signs and symptoms, and are issued with a patient alert card, which carries important safety information on any side effects you may experience. When at home, if you believe your MS is getting worse or you notice any new symptoms appear after an infusion you should speak to your doctor immediately.

As at 3rd December 2014 the overall risk of developing PML, based on post-marketing experience, is estimated at 3.78 in 1000. Rounding up or down to an integer value is at your discretion. For patients that haven't been exposed to the JC virus the estimated risk is still 1 in 10,000. Variance over time has shown to be small enough to justify quarterly analysis rather than monthly.

Should I switch from the MS therapy I am already on to Tysabri?

Only you can answer this question in discussion with your neurologist. You need to consider if you meet the criteria, the risks of side effects (including PML) and how well you are doing on your current therapy.

Do not use TYSABRI

- If you are allergic to natalizumab or any of the other ingredients of this medicine.
- If your doctor has told you that you have PML (progressive multifocal leukoencephalopathy). PML is a rare infection of the brain.
- If your doctor tells you that you have a serious problem with your immune system (due to disease for example, HIV or due to a medicine you are taking or have previously taken, e.g. mitoxantrone or cyclophosphamide).
- If you are taking either beta-interferon or glatiramer acetate. These medicines are for MS and cannot be used with Tysabri.
- If you have an active cancer (unless it is a type of skin cancer called basal cell carcinoma).
- If you are under 18 years of age.

Disclaimer:

MS Ireland provides information to the MS Community on an array of topics associated with MS. This information is for reference purposes only and medical advice should always be sought before any treatment or intervention is tried.

Source:

www.msdecisions.org.uk

This information has been taken from Patients Information Leaflet.