



THE USE OF NATALIZUMAB (TYSABRI) FOR THE TREATMENT OF MULTIPLE SCLEROSIS

The drug natalizumab (Tysabri) has been approved for use in people with relapsing multiple sclerosis (MS), but it also has been linked to an increased risk of developing progressive multifocal leukoencephalopathy (PML), a rare and usually fatal viral disease. This fact sheet will help you and your family understand the use of natalizumab for treatment of multiple sclerosis.

Neurologists from the American Academy of Neurology (AAN) are doctors who identify and treat diseases of the brain and nervous system. The following evidence-based information* is provided by experts in neurology who carefully reviewed all available evidence on the use of natalizumab for multiple sclerosis.

Does natalizumab effectively treat MS? Who should take it?

Strong evidence suggests that natalizumab lessens how active and severe your MS is. However, natalizumab therapy may raise your risk of developing PML. For this reason, natalizumab should be given only to people with relapsing MS who have not found relief with other therapies (they continued to have disease activity, could not tolerate the drug, or have had a particularly aggressive initial disease course).

Does taking natalizumab raise the risk of developing PML?

Studies suggest that one person will develop PML for every 1,000 people who take natalizumab for about 18 months. However, because this drug has not been in use for very long, more studies on possible risks are needed.

Does combining natalizumab with other drugs raise the risk of developing PML?

Strong evidence suggests that combining natalizumab with interferon-beta may raise the risk of PML, so this combination should not be used.

How does natalizumab compare to other drugs for MS?

There is not enough evidence to show how effective natalizumab is in treating MS when compared with other MS drugs.

Is natalizumab effective for other types of MS, such as secondary progressive MS?

There is not enough evidence to show whether natalizumab effectively treats secondary progressive MS.

This is an educational service of the American Academy of Neurology (AAN). It is designed to provide members with evidence-based guideline recommendations to assist with decision-making in patient care. It is based on an assessment of current scientific and clinical information and is not intended to exclude any reasonable alternative methodologies. The AAN recognizes that specific patient care decisions are the prerogative of the patient and the physicians caring for the patient, based on the circumstances involved. Physicians are encouraged to review carefully the full AAN guidelines so they understand all recommendations associated with care of their patients.

* After the experts review all of the published research studies, they describe the strength of the evidence supporting each recommendation:

Strong evidence = more than one high-quality scientific study

Good evidence = at least one high-quality scientific study or two or more studies of a lesser quality

Weak evidence = the studies, while supportive, are weak in design or strength of the findings

Not enough evidence = either different studies have come to conflicting results or there are no studies of reasonable quality

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