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**EPAR summary for the public**

# Tysabri

natalizumab

This is a summary of the European public assessment report (EPAR) for Tysabri. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Tysabri.

For practical information about using Tysabri, patients should read the package leaflet or contact their doctor or pharmacist.

## What is Tysabri and what is it used for?

Tysabri is a medicine for treating adults with multiple sclerosis (MS) that has failed to respond to another disease-modifying therapy or is rapidly getting worse.

Multiple sclerosis is a disease of the nerves, in which inflammation destroys the protective sheath surrounding the nerve cells.

Tysabri is used in the type of MS known as 'relapsing-remitting' MS, when the patient has attacks (relapses) in between periods with no symptoms (remissions).

It contains the active substance natalizumab.

## How is Tysabri used?

Treatment with Tysabri should be started and continuously supervised by a doctor who is experienced in treating diseases of the nervous system and has access to a magnetic resonance imaging (MRI) scanner. This scanner will enable the doctor to check for changes in the brain or spinal cord linked to MS or to the brain infection called progressive multifocal leukoencephalopathy (PML), which has been associated with Tysabri and other MS medicines.

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Tysabri is given as a one-hour infusion (drip) into a vein once every four weeks. Because the infusion can trigger an allergic reaction, the patient must be monitored during the infusion and for one hour afterwards. If there is no clear benefit for the patient after six months, the doctor should re-assess the treatment.

The medicine can only be obtained with a prescription.

## How does Tysabri work?

The active substance in Tysabri, natalizumab, is a monoclonal antibody which targets a protein called 'α4β1 integrin' found on the surface of white blood cells involved in inflammation. By attaching to integrin, natalizumab is thought to stop white blood cells from going from the blood to the brain tissue, thereby reducing inflammation and nerve damage caused by MS.

## What benefits of Tysabri have been shown in studies?

Tysabri was effective at reducing the number of relapses and the worsening of disability (as measured with the Expanded Disability Status Scale).

In a study comparing Tysabri with placebo (a dummy treatment), the number of MS attacks in Tysabri-treated patients fell by about 68% after a year, compared with the patients who received placebo. In addition, the risk of disability getting worse was reduced by 42% over two years with Tysabri in comparison with placebo.

A second study showed that adding Tysabri to treatment with another medicine, interferon beta-1a, was more effective than adding placebo, reducing the risk of disability getting worse and the number of relapses.

Finally, a third study, still ongoing, has shown the average number of MS attacks per year falling from 1.99 to 0.22 in Tysabri-treated patients (regardless of which disease-modifying treatment they had previously used),. The response was maintained for up to 5 years.

## What are the risks associated with Tysabri?

Tysabri can increase the risk of infections, including the brain infection PML. PML is a very serious condition that may result in severe disability or death. The risk of PML increases the longer a patient has been receiving Tysabri, especially in patients treated for more than two years. The risk is also higher if the patient used medicines that supress the immune system before starting Tysabri, or if the patient has antibodies against the virus that causes PML. If PML is suspected, the doctor must stop treatment until it is certain that the patient does not have the infection.

The most common side effects seen in studies with Tysabri (seen in between 1 and 10 patients in 100) were urinary tract infection (infection of the structures that carry urine), nasopharyngitis (inflammation of the nose and throat), urticaria (itchy rash), headache, dizziness, vomiting, nausea (feeling sick), joint pain, rigors (shaking chills), fever and tiredness. For the full list of all side effects reported with Tysabri, see the package leaflet.

About 6% of the patients in studies developed long-lasting antibodies against natalizumab, which reduced the medicine's effectiveness.

Tysabri must not be given to patients who have PML or who are at risk of getting an infection, including patients whose immune system is weakened. It must not be given in combination with other disease-modifying medicines or to patients who have cancer (unless it is a type of skin cancer called basal cell carcinoma).

## Why is Tysabri approved?

Studies have shown that Tysabri is effective in treating relapsing-remitting MS. However, because of its safety risks, it should only be used in patients who have a real need for the medicine either because their disease has failed to respond to at least one other disease-modifying therapy or is rapidly getting worse.

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Tysabri's benefits in this restricted population are greater than its risks and recommended that it be given marketing authorisation.

## What measures are being taken to ensure the safe and effective use of Tysabri?

The company that markets Tysabri will agree on measures to further enhance the monitoring of patients with each Member State, such as registries and studies of patients receiving Tysabri. It will also supply all doctors who prescribe Tysabri with an educational pack that includes information on the safety of Tysabri, including information on which patients may be at a higher or lower risk of PML. Patients should receive this information when starting Tysabri, when continuing treatment for longer than 2 years, and when stopping treatment, as the risk of PML persists for 6 months after stopping treatment. The pack will also include information about other risks of this medicine for patients.

Patients who receive Tysabri must be given a special alert card that summarises the key safety information about the medicine. Patients should read this card carefully and keep it with them. Patients should make sure their partner or carer, as well as other doctors treating them, are aware of its content.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Tysabri have also been included in the summary of product characteristics and the package leaflet.

## Other information about Tysabri

The European Commission granted a marketing authorisation valid throughout the European Union for Tysabri on 27 June 2006.

The full EPAR for Tysabri can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Tysabri, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 04-2017.