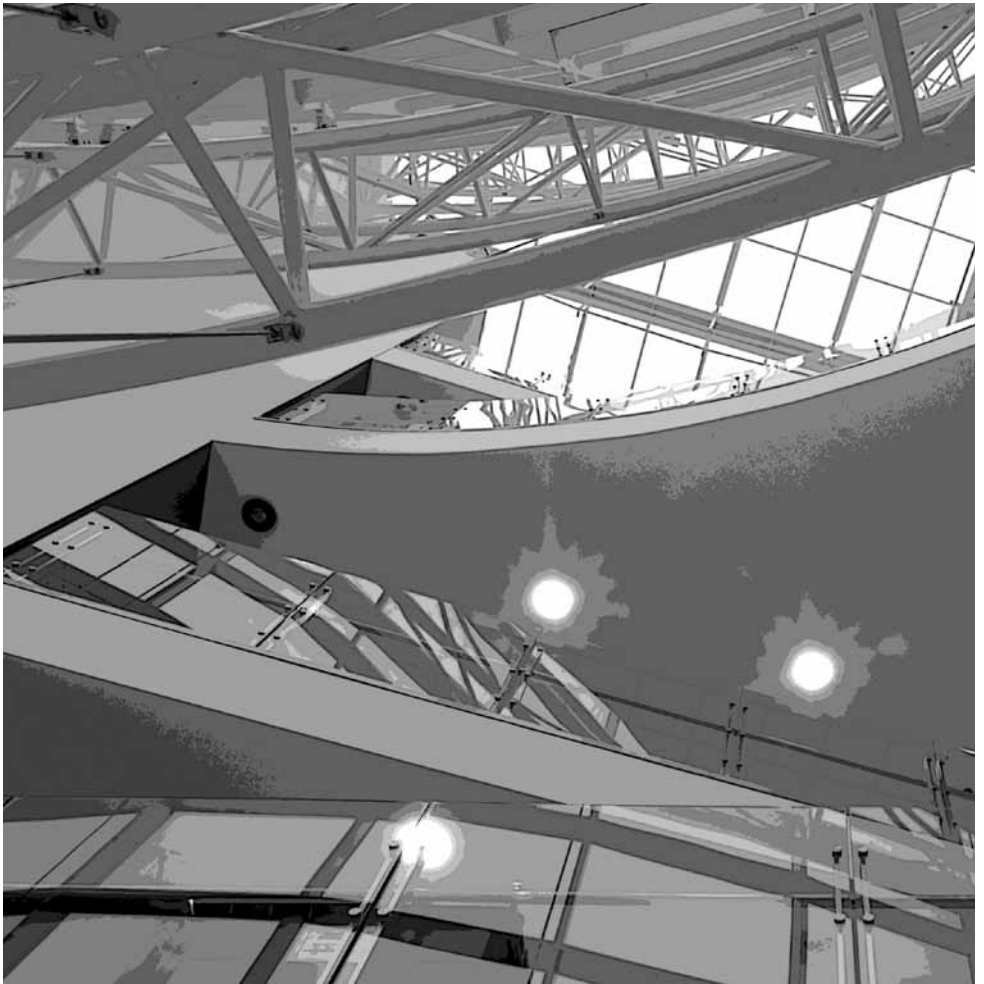


Department of Neurology
Natalizumab (Tysabri)
for Multiple Sclerosis
Information for patients



What is Natalizumab and what is it used for?

Natalizumab is an artificial antibody and is used to treat Multiple Sclerosis. It is used:

- to reduce relapses
- to reduce worsening of disability in relapsing remitting patients who have significant relapses.
- for patients with rapidly evolving, severe, relapsing remitting Multiple Sclerosis (defined by two or more disabling relapses in the year and supportive MRI brain scan changes).

Natalizumab works by preventing the cells that cause inflammation from entering the brain, and this reduces nerve damage caused by the disease. In clinical trials natalizumab decreased the number of MS attacks by about two thirds.

Natalizumab cannot repair the damage that has already been caused, and when you receive the drug you may not notice any improvement in pre-existing symptoms. However, the drug may still be working to stop your MS becoming worse. It is not a treatment for progressive MS.

How is it given?

Natalizumab is an intravenous preparation. It is given on the ward once every four weeks as a drip into a vein in the arm. This usually takes about an hour, and we would like you to spend a further hour on the ward after the infusion to make sure that you do not have an allergic reaction to the treatment. You should normally expect to be in the hospital for half a day.

Possible side effects

Allergic reaction

Occasionally natalizumab can cause an allergic reaction during or immediately after treatment. This reaction usually starts within 2 hours of the start of the infusion, with hypersensitivity, i.e. itching or rash, in up to 4% of people, and significant allergic reactions in less than 1% of people. You should report to the doctor or the nurse administering the drug if you feel any the following side effects:

- itchy rash
- swelling of your face, lips or tongue
- difficulty breathing.

Common side effects

The following side effects happen in less than 1 in 10 patients:

- urinary tract infection
- sore throat and runny or blocked up nose
- shivering
- itchy rash
- headache
- dizziness
- nausea
- vomiting
- joint pain
- fever
- fatigue.

Rare side effects

Natalizumab can also cause rare side effects including unusual (or “opportunistic”) infections, e.g. PML (see below). An ‘opportunistic infection’ is an illness caused by an organism that does not usually cause disease in a person with a normal immune system.

We will give you **a patient alert card, which you must carry with you at all times**, which lists the symptoms you must report straight away. As you may develop a serious infection while you are taking Natalizumab, please report to your GP or MS Specialist Nurse if you have any of the following:

- an unexplained fever
- severe diarrhoea
- shortness of breath
- prolonged dizziness
- significant or intense headache
- stiff neck
- weight loss
- listlessness
- progressive multi-focal leukoencephalopathy (**PML** – see below).

Progressive multi-focal leukoencephalopathy (PML)

PML is a very serious disease of the central nervous system. It is caused by the ‘JC’ virus. It usually leads to severe disability or death. It can occur in people treated with natalizumab.

The risk of developing PML depends on the duration of use of natalizumab; the risk rises after 2 years on treatment.

The average risk of developing PML is:

0.03/1000 (or 0.3 in 10,000) in year 1

0.5/1000 (or 5 in 10,000) in year 2

1.9/1000 (or 19 in 10,000) in year 3

There is less data about year 4, but the risk probably remains similar to year 3. The risk beyond 4 years is unknown at present.

We can now do a test to check whether the PML risk for you is higher or lower than the average risks given above. About 50% of normal people carry JC virus but it is kept in check by their immune system so that they remain healthy. PML occurs when natalizumab depresses the immune system allowing the JC virus to activate. You will be tested to check whether you carry the virus (using a blood antibody test) before treatment.

People with a **negative** antibody test (who do **not** carry the virus) have a very low risk of developing PML when on natalizumab. The risk over 4 years of treatment is estimated at 0.11/1000 (or 1.1 in 10,000).

However the risk of developing PML is increased in people who **do** carry the virus (i.e. who have a **positive** antibody test). The risks are about double those listed earlier.

People who have received immunosuppressant medication* in the past have an even higher risk; it is very important to notify the doctor if you have received any of these drugs in the past. (* Immunosuppressant treatments include: Mitoxantrone, Azathioprine, Methotrexate, Cyclophosphamide, Mycophenolate, Cladribine, Rituximab.)

Because the symptoms of PML may be similar to an MS relapse, **it is very important that you report any new symptoms or any progression in your MS.** We may have to carry out tests (MRI) to distinguish the cause of these symptoms.

There is no proven treatment for patients who develop PML following treatment with natalizumab, but it is thought that early recognition of the condition and cessation of treatment may improve the outcome.

Other Rare Side effects

Natalizumab is a new and powerful medication. It is possible that other important and unusual side effects have not yet been recognised.

Alternatives

There are alternative drugs which can be used as disease modifying therapies in Multiple Sclerosis which will be discussed with you in the clinic.

Pregnancy and breast feeding

There is no adequate data on the use of natalizumab in pregnant women, and the potential risk for humans is unknown. Natalizumab should not be used in pregnancy, nor during breast feeding. If you think you may be pregnant, or if you wish to consider pregnancy in the future, please discuss this with the Specialist Nurse or Doctor.

How to contact the MS Specialist Nurses

MS specialist nurse helpline:

Tel: **01865 234461** (Answerphone, answered regularly between 9am - 5pm on normal working days.)

In an emergency please contact your GP who can liaise with the on-call Neurologist if necessary.

If you need an interpreter or need a document in another language, large print, Braille or audio version, please call **01865 221473** or email **PALSJR@ouh.nhs.uk**

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