

Switching from Tysabri® to Tyruko® for patients with relapsing remitting multiple sclerosis

Patient Information Sheet

This material has been developed to provide you with information that enables you to ask your healthcare team questions about your treatment. This is a key part of shared decision making - the joint process in which a healthcare professional works together with a person to reach a decision about their care and treatment options. It ensures that tests and treatments are jointly chosen based on evidence and what matters to the person, their individual goals, preferences, beliefs and values.

Summary

- Some patients with relapsing remitting multiple sclerosis (RRMS) are currently being switched between two versions of the drug natalizumab - from Tysabri® to the biosimilar Tyruko®.
- Health regulators have determined that there are no meaningful differences between the two medicines in terms of quality, safety and how effective they are.
- All versions of natalizumab can cause similar side effects and should be reported via the Yellow Card scheme as with all medicines (<https://yellowcard.mhra.gov.uk/>).
- Some patients may see a change in their John Cunningham (JC) virus test result when switching to the biosimilar Tyruko. This is because a different test is used for Tyruko.
- Please speak to your MS team if you notice any changes in your test results or have any other questions.

What is natalizumab?

Natalizumab is a medication used to treat some patients with relapsing remitting multiple sclerosis (RRMS). Natalizumab works by stopping white blood cells getting through to the brain, reducing inflammation in the brain and spinal cord in multiple sclerosis (MS).

It is often given as an intravenous infusion (“a drip”, via a small tube placed in a vein). This is normally given in a hospital infusion clinic (day-case unit) and takes two to three hours.

Natalizumab is a type of medicine known as a biological medicine. A biological medicine is a medicine that is derived from a biological (living) source, such as bacteria or viruses, blood, tissues or living cells in culture.

There are currently two brands of natalizumab: Tysabri® and Tyruko®. Tysabri is the original medicine approved for use in the NHS in England in 2007. Tyruko is a biosimilar medicine, approved for use in the NHS in England in 2023.

Biosimilar medicines

Biosimilar medicines contain a version of the active substance of an approved biological medicine.

When the patent of a biological medicine expires, other manufacturers can produce and sell biosimilar medicines that work in the same way as the original drug. This usually means the medicine can be purchased at a lower cost to the NHS.

Biosimilar medicines go through the same approvals process as the original medicine and must be shown to have no clinically meaningful difference in their quality, safety and how effective they are. The safety of all NHS medicines is confirmed by the Medicines and Healthcare products Regulatory Agency (MHRA).

This means biosimilar medicines can be used in place of the original drug. Patients will continue to receive the same medication, produced by a different manufacturer.

Switching from Tysabri to Tyruko

Some patients who have previously received Tysabri are currently being switched to the biosimilar medicine Tyruko. The decision to change your medication should always be overseen by the consultant leading your care.

Both versions of natalizumab can cause similar side effects. However, as with all medicines, these can vary and may be different between different people. If you have side effects, you should discuss these with your MS team.

You and your MS team can report side effects of any medicine or any adverse incident relating to a medical device (including John Cunningham virus tests) via the Yellow Card scheme (<https://yellowcard.mhra.gov.uk/>). This ensures concerns are notified to the MHRA.

John Cunningham Virus and Progressive Multifocal Leukoencephalopathy

John Cunningham (JC) virus is a common virus in the general population. You are unlikely to know if you have been infected as JC virus causes no symptoms and is normally kept under control by the immune system.

However, if your immune system is weakened, the JC virus can reactivate. It can then cause inflammation and damage to the brain resulting in a serious illness called Progressive Multifocal Leukoencephalopathy (PML).

Treatment with natalizumab can increase the risk of developing PML. This is because natalizumab can affect your immune system.

If you are identified as being at a higher risk, you will be carefully monitored for any signs of PML. This could mean more frequent blood testing to check for JC virus, or MRI scans to detect PML at an early stage.

Testing for John Cunningham Virus

When you receive natalizumab, your blood will be regularly tested to detect the immune response against JC virus. Your MS team will use this to help work out what your risk of PML might be.

If you are receiving Tysabri, then the StratifyJCV® test is used. If you are receiving Tyruko, then the ImmunoWELL® JCV test is used. Evidence suggests that the two tests may produce different results.

Although a change in your test result may cause anxiety, for most people, a change in result will likely be due to the differences between the two tests and will be monitored by your MS team.

If you are informed of a change in antibody status or test result after switching JC virus tests, you should speak to your MS team to discuss the significance of this and whether this has any implications for your monitoring or treatment.

Further information

- Medicines & Healthcare products Regulatory Agency (MHRA) website: <https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency>
- National Institute of Health and Care Excellence (NICE) technology appraisal guidance of natalizumab for the treatment of adults with highly active relapsing-remitting multiple sclerosis: <https://www.nice.org.uk/Guidance/TA127>
- The Patient's Association website: <https://www.patients-association.org.uk/switchingtobiosimilars>
- Biosimilar medicines: [NHS England » What is a biosimilar medicine?](#)
- Shared decision making: [NHS England » Shared decision-making](#)

If you have further questions about natalizumab or biosimilars, then please speak to a member of your neurology or pharmacy team.