EMA/359827/2023
EMEA/H/C/005752

Tyruko (*natalizumab*)

An overview of Tyruko and why it is authorised in the EU

What is Tyruko and what is it used for?

Tyruko is a medicine used in adults to treat highly active multiple sclerosis (MS) that is rapidly getting worse or that is not sufficiently controlled with at least one other disease-modifying therapy (a therapy that can modify the course of the disease).

MS is a disease of the nerves, in which inflammation destroys the protective sheath surrounding nerves and damages the nerves themselves.

Tyruko is used in relapsing-remitting MS, a type of MS in which the patient has attacks (relapses) between periods of stable symptoms (remissions).

Tyruko is a 'biosimilar medicine'. This means that Tyruko is highly similar to another biological medicine (the 'reference medicine') that is already authorised in the EU. The reference medicine for Tyruko is Tysabri. For more information on biosimilar medicines, see here.

Tyruko contains the active substance natalizumab.

How is Tyruko used?

The medicine can only be obtained with a prescription and treatment with Tyruko should be started and 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 a brain infection called progressive multifocal leukoencephalopathy (PML), which has been associated with natalizumab and other MS medicines.

Tyruko is given as a 1-hour infusion (drip) into a vein once every 4 weeks. Because the infusion can trigger an allergic reaction, the patient must be monitored during the infusion and for 1 hour afterwards. If there is no clear benefit for the patient after 6 months, the doctor should re-assess the treatment with Tyruko.

For more information about using Tyruko, see the package leaflet or contact your doctor or pharmacist.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

How does Tyruko work?

The active substance in Tyruko, natalizumab, is a monoclonal antibody which targets a protein called α4β1 integrin on white blood cells involved in inflammation. By attaching to this protein, natalizumab is thought to stop white blood cells from entering the brain and spinal cord tissue, thereby reducing inflammation and the resulting nerve damage. This helps to reduce symptoms of the disease.

What benefits of Tyruko have been shown in studies?

Laboratory studies comparing Tyruko with Tysabri have shown that the active substance in Tyruko is highly similar to that in Tysabri in terms of structure, purity and biological activity. Studies have also shown that giving Tyruko produces similar levels of the active substance in the body to giving Tysabri.

In addition, a study in 265 patients with relapsing-remitting MS showed that Tyruko produced comparable improvements to those seen with Tysabri. In this study, the average number of new lesions (abnormality) in the brain, as measured by MRI after 24 weeks of treatment, was 1.4 with Tyruko and 1.9 with Tysabri.

Because Tyruko is a biosimilar medicine, the studies on effectiveness and safety of natalizumab carried out with Tysabri do not all need to be repeated for Tyruko.

What are the risks associated with Tyruko?

The safety of Tyruko has been evaluated, and on the basis of all the studies carried out the side effects of the medicine are considered to be comparable to those of the reference medicine Tysabri.

For the complete list of side effects and restrictions of Tyruko, see the package leaflet.

Tyruko 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 Tyruko, especially in patients treated for more than 2 years. The risk is also higher for patients who used medicines that supress the immune system before starting Tyruko, 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 this infection.

The most common side effects with Tyruko (which may affect more than 1 in 10 people) are urinary tract infection (infection of the parts of the body that carry urine), nasopharyngitis (inflammation of the nose and throat), headache, dizziness, nausea (feeling sick), joint pain and tiredness.

Patients may develop long-lasting antibodies against natalizumab, which reduces the medicine’s effectiveness.

Tyruko 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 skin cancer called basal cell carcinoma).

Why is Tyruko authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Tyruko has a highly similar structure, purity and biological activity to Tysabri and is distributed in the body in the same way. In addition, studies in patients with relapsing-remitting MS

have shown that the safety and effectiveness of Tyruko is equivalent to that of Tysabri in this indication.

All these data were considered sufficient to conclude that Tyruko will behave in the same way as Tysabri in terms of effectiveness and safety in its authorised uses. Therefore, the Agency's view was that, as for Tysabri, the benefits of Tyruko outweigh the identified risks and it can be authorised for use in the EU.

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

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

Patients who receive Tyruko 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 Tyruko have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Tyruko are continuously monitored. Suspected side effects reported with Tyruko are carefully evaluated and any necessary action taken to protect patients.

Other information about Tyruko

Tyruko received a marketing authorisation valid throughout the EU on 22 September 2023.

Further information on Tyruko can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/tyruko.

This overview was last updated in 09-2023.