SANDOZ

Natalizumab 300 mg
Concentrate for solution for infusion

Treatment Initiation Form

EU-RMP1.2May2023

This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA - Version 1.2

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TYRUKO (natalizumab)

TREATMENT INITIATION FORM

Please read this form carefully before initiating treatment with TYRUKO. This form provides advice and information to ensure that you understand the important safety information of natalizumab treatment such as risk of PML (progressive multifocal leukoencephalopathy), IRIS (immune reconstitution inflammatory syndrome) and others.

You should do the following before starting the treatment with TYRUKO:

- **Read the Patient Leaflet**
- **Have a discussion with your doctor about the benefits and risks associated with this treatment.**
- **Read the Patient Alert Card**

PML is a rare brain infection that has occurred in patients receiving natalizumab therapy, which can lead to severe disability or death. Both Patient Leaflet and Patient Alert Card provide important safety information about PML.

John-Cunningham (JC) virus is a common virus, which infects many people but usually does not cause a harmful illness. The reason for the uncontrolled increase of JC virus in the brain resulting in PML in some patients treated with natalizumab is unknown.

The risk of developing PML in natalizumab-treated patients is higher:

- If you have presence of antibodies against JC virus in your blood
- when treatment with natalizumab is longer, especially beyond 2 years
- If you have previously been treated with a medicine that reduces the activity of your immune system (an immunosuppressant medicine) before starting treatment with natalizumab.

The potential PML risk should be discussed between you and your doctor before you start treatment with TYRUKO.

Your blood may be tested to check if you have antibodies against JC virus before you start your treatment with TYRUKO. To check if anything has changed the test may be repeated while you are on TYRUKO treatment. The PML risk is higher if:

If you have all three risk factors listed above, or if the levels of JC virus antibodies are higher and you have been on natalizumab treatment for more than 2 years, and if you have not taken an immunosuppressant medicine prior to starting TYRUKO.
You will be more closely monitored by your doctor if your risk for PML is higher.

Before you start your treatment with TYRUKO and when you have been on natalizumab therapy for more than 2 years, you should discuss with your doctor if TYRUKO is the most suitable medicine for you.

IRIS (immune reconstitution inflammatory syndrome) is a rare reaction, which is likely to occur in patients after being treated for PML, when natalizumab treatment is removed from your body. IRIS may lead to worsening of your condition, including your brain function getting worse.

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Patient´s Name (print) _____

Patient's´ Signature_____**Date:**_____

Doctor´s Name (print)_____

Doctor´s Signature_____**Date:**_____

PML risk estimation:

Patients who are anti-JCV antibody negative

If you do not have antibodies against JC virus your chance of getting PML is low (approximately 1 in 10.000 patients), based on global data.

Patients who are anti-JCV antibody positive

Your risk of developing PML will vary when you have antibodies against JC virus and will depend on the duration of the treatment with natalizumab, the level of anti-JCV antibodies and if you have received previous treatment with an immunosuppressant medicine. The potential risk will be discussed with your doctor before starting your treatment.

Reporting of side effects:

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in the patient leaflet. You can also report side effects directly via the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

Sandoz reporting adverse events:
Email:
adverse.event.sau@sandoz.com
Website: https://pvi1j.solutions.iqvia.com/pvi-web/

Saudi Food and Drug Authority National Pharmacovigilance Center
Unified Contact Center: 19999
Email: npc.drug@sfda.gov.sa
Website: https://ade.sfda.gov.sa

This document has been approved by Saudi Food and Drug Authority (SFDA).

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