SANDOZ

Natalizumab 300 mg
Concentrate for solution for infusion

Patient Alert Card

EU-RMP1.2May2023

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

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PATIENT ALERT CARD

This card contains important safety information that you need to be aware of before you are given TYRUKO (natalizumab), during treatment and after stopping treatment with TYRUKO. TYRUKO increases the risk of a rare brain infection called progressive multifocal leukoencephalopathy (PML). Please carry this card with you.

- Present this TYRUKO alert card to all doctors you see, not only to your neurologist at a hospital, but also if you go to the Emergency Room, or to any other healthcare professional that is not your usual treating team (i.e., Neurologist, MS or Infusion Nurse).
- Carefully read the TYRUKO Patient Leaflet before starting your treatment.
- This alert card should be kept with you during your treatment with TYRUKO. It is important that you keep this card for at least 6 months after you have received the last dose of TYRUKO, because side effects may occur even after the treatment with TYRUKO is stopped.

You will have JC virus blood tests and MRI scans before and during treatment. Attend all scheduled monitoring appointments.
Present this card to your partner or caregivers because they might see PML symptoms that you might not recognize such as changes in your mood or behavior, memory failure and difficulties with speech and communication. Symptoms might occur for up to 6 months after discontinuing treatment with TYRUKO. It is important you and your partner or caregivers remain aware of these symptoms this whole time.

Before starting the treatment with TYRUKO following evaluations need to be considered:

- If you have a severe problem with your immune system, you should not be treated with TYRUKO
- While you are getting the treatment with TYRUKO, Do not use TYRUKO with other medicines that affect your immune system, including certain MS medicines, unless your specialist confirms it is appropriate.

During treatment with TYRUKO

Risk of Progressive Multifocal Leukoencephalopathy (PML)

Natalizumab is thought to increase the risk of PML, a rare brain infection, which has occurred in patients who have been on natalizumab therapy. PML commonly results in severe disability or death.

The PML risk emerges with the duration of natalizumab treatment, especially after 2 years.

PML symptoms may be similar to Multiple Sclerosis (MS) relapse. That is why it is very important that you call or see your doctor at the earliest if you feel your MS is worsening or if you notice any new symptoms during and for up to 6 months after stopping your TYRUKO treatment. Symptoms of PML normally develop slower (over days or weeks) than those related to a MS relapse, however they may be comparable to your MS symptoms.
It is important to be aware of the following PML signs

- Changes in behavior
- Changes in concentration and mental capacity
- Problems with your vision
- Muscle weakness on one side of the body
- New neurological symptoms that you have not experienced before such as confusion and memory loss

Management of PML requires an "immediate stop" of TYRUKO treatment.

Be aware of symptoms of other serious infections

Other serious infections may also occur with natalizumab treatment. You should call or see your doctor at the earliest convenience if you think you are experiencing signs of a persistent, severe infection, for example constant fever.

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Contact Details

Patient:

Name:

Treating Doctor:

Name:

Phone:

Start date of TYRUKO treatment:

Reporting of side effects:

It is important that you tell your doctor if you have any side effects. This also includes any probable side effects, which are not yet listed in the patient leaflet. You can also report side effects directly via the national reporting system.

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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