SANDOZ

Natalizumab 300 mg
Concentrate for solution for
infusion

Treatment Discontinuation 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 DISCONTINUATION FORM

This form provides advice and information to ensure that you understand and are fully informed of the continued risk of PML (progressive multifocal leukoencephalopathy) for up to 6 months after discontinuation of natalizumab treatment.

Before starting treatment with TYRUKO a Patient Alert Card, which contains valuable information about PML, should have been given to you by your doctor for your reference. You should keep this Patient Alert Card for 6 months following discontinuation of treatment. The card contains important safety information, especially any symptoms you may develop, which could indicate PML, therefore you should keep the Alert Card with you and if appropriate show it to your partner or caregiver. Please ask your doctor to provide you with a Patient Alert Card that you received when starting TYRUKO if you do not have it anymore.

PML is a rare brain infection that has occurred in patients receiving natalizumab therapy and can lead to severe disability or death. PML has been reported up to 6 months after discontinuation of natalizumab treatment.

PML signs include:

- Changes in behavior
- Changes in concentration and mental ability
- Problems with your vision
- Weakness on one side of the body
- New neurological symptoms that you have not experienced before

PML symptoms may be similar to a Multiple Sclerosis (MS) relapse. It is especially important that you speak with your doctor at the earliest if you feel your MS is worsening or if you notice any new symptoms for up to 6 months after stopping TYRUKO treatment.

During the 6 months period after discontinuation of treatment with TYRUKO, you will be monitored by your doctor who will decide when you should receive MRI imaging. Normally, you will continue to have MRI imaging every 3-6 months if you have one or the other of the two combinations of PML risk factors:

- You have taken natalizumab treatment for more than 2 years, have antibodies against the JC virus and have previously taken an immunosuppressant medicine (a medicine that reduces the activity of your body´s immune response) at any time before starting TYRUKO.
- You have taken natalizumab treatment for more than 2 years, have an increased amount of JC virus antibodies in your blood and have never taken an immunosuppressant medicine before starting treatment with TYRUKO.

If none of the above combinations is applicable to you then you will continue to receive MRI imaging routinely as prescribed by your doctor.

Please ask your doctor if you have any questions about the information above.

Patient´s Name (print) _____

Patient´s Signature_____**Date:**_____

_____

Doctor´s Name (print)_____

Doctor´s Signature_____**Date:**_____

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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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