TYSABRI (natalizumab) Treatment Discontinuation Form

This form is a risk awareness dialogue that should be read carefully before discontinuing treatment with TYSABRI. Please follow the advice in this form to ensure that you are fully informed of and understand the continued risk of PML (progressive multifocal leukoencephalopathy) for up to 6 months following discontinuation of TYSABRI.

Before starting treatment with TYSABRI you should have received a Patient Card from your doctor. This Patient Card should be kept for 6 months after discontinuation of treatment as it has important information about PML for your reference.

PML is an uncommon brain infection that has occurred in patients who have been given TYSABRI, and which may lead to severe disability or death. PML has been reported up to 6 months after discontinuation of TYSABRI.

Signs include:
- changes in mental ability and concentration,
- behavioural changes,
- weakness on one side of the body,
- vision problems,
- New brain or nerve related symptoms that are unusual for you.

Symptoms of PML may be similar to a MS relapse. Therefore, if you believe your MS is getting worse or if you notice any new symptoms for up to 6 months after stopping TYSABRI treatment, it is very important that you speak to your doctor as soon as possible

During the 6 months following treatment discontinuation of TYSABRI, your doctor will monitor you and will decide when you should receive MRI imaging. In general, you will continue to receive 3-6 month MRI imaging if you have either of the following combination of PML risk factors:

- You have antibodies to the JC virus, have taken TYSABRI for more than 2 years and previously taken an immunosuppressant (a medicine that reduces the activity of your body's immune system) at any time before starting TYSABRI.
- You have never taken an immunosuppressant therapy before starting TYSABRI, but have taken TYSABRI for more than 2 years and have a high anti-JCV antibody index (increased amount of antibody in your blood).

If you do not fall into one of the above groups, then you will continue to receive routine MRIs as prescribed by your doctor.

Should you have any questions about the above information, please ask your doctor.

If you do not have the Patient Card that you received when starting TYSABRI, then please ask your doctor for a new card. You should keep the Patient Card with you to remind you of the important safety information, in particular any symptoms you may develop which could possibly indicate PML, if appropriate, you should show the Patient Card to your partner or caregiver.

[***Patient's name, signature and date of signature, and Doctor's name, signature, and date of signature***].

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the national reporting system (https://medicinesauthority.gov.mt/adrportal) OR to Pharma.mt Ltd (obo Biogen – MAH): pharmacovigilance@pharmamt.com.

By reporting side affects you can help provide more information on the safety of this medicine.

Approved by the Malta Medicines Authority on the 29th May 2026.