

Tysabri® (natalizumab)	Adverse drug event reporting channels: Malta Medicines Authority: https://medicinesauthority.gov.mt/adrportal OR Pharma.mt Ltd (obo Biogen – MAH): pharmacovigilance@pharmamt.com
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Pre-Administration Checklist

**Educational Material for Healthcare Professionals (HCPs), patients and caregivers
For Use Prior to Administration of TYSABRI™ Subcutaneously (SC) Outside a Clinical
Setting**

PML, an uncommon brain infection, has occurred in patients who received TYSABRI. The goal of the Pre-administration checklist is to review signs and symptoms of PML before injecting Tysabri. This Pre-administration Checklist is not intended as a replacement for any local pre-administration health checks or screening by HCPs.

Before using this checklist:

- **HCPs** should review the EU TYSABRI SC Summary of Product Characteristics (SmPC) and “Tysabri (Natalizumab) Healthcare Professional Guide”
- **Patients and caregivers** should review the Package Leaflet and Patient Card

PRE-ADMINISTRATION CHECKLIST			
#	QUESTION	IF YES TO ANY	IF NO TO ALL
1	Since your last dose of TYSABRI, have you had any new or worsening of the following symptoms? <ul style="list-style-type: none"> • Changes in mental ability and concentration • Behavioral changes • Weakness on one side of the body • Vision problems • New brain or nerve related symptoms that are unusual for you 	 Do NOT inject TYSABRI SC. Contact the Specialist Doctor immediately.	 You may inject Tysabri SC
2	Since your last dose of TYSABRI, have you been diagnosed with a new medical condition or had a surgery that can weaken your immune system?		
3	Since your last dose of TYSABRI, have you taken new medicines for multiple sclerosis (MS) or other medicines that can weaken the immune system?		