



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, a rare 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 HCP Informational Supplement
- **Patients and caregivers** should review the Package Leaflet and Patient Alert Card

PRE-ADMINISTRATION CHECKLIST			
#	QUESTION	IF YES TO <u>ANY</u>	IF NO TO <u>ALL</u>
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 	<div style="text-align: center;">  Do <u>NOT</u> inject TYSABRI SC. Contact the Specialist Doctor immediately. </div>	<div style="text-align: center;">  You may inject Tysabri SC </div>
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?		