

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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<p align="center"><u>TYSABRI Patient Alert Card</u></p> <p>Patient's Name: _____ Doctor's Name: _____ Doctor's Phone: _____ Date TYSABRI Started: _____</p> <p>This alert card contains important safety information that you need to be aware of before, during and after stopping treatment with TYSABRI.</p> <ul style="list-style-type: none"> • Show this card to any doctor involved with your treatment, not only to your neurologist. • Please read the TYSABRI 'Package Leaflet' carefully before you start using this medicine. • Keep this card with you during Tysabri treatment and 6 months after the last dose of TYSABRI, since side effects may occur even after you have stopped treatment with TYSABRI. • Show this card to your partner or caregivers. They might see symptoms of PML that you might not notice, such as changes in mood or behaviour, memory lapses, speech and communication difficulties. You should remain aware of symptoms that might arise for up to 6 months after stopping TYSABRI treatment. • If you self-administer TYSABRI using prefilled syringes or a caregiver administers it to you, the list of PML symptoms should be reviewed before each dose. Please review the Pre-Administration checklist before administering TYSABRI. <p align="center"><u>Prior to treatment with TYSABRI</u></p>	<p align="center"><u>During treatment with TYSABRI</u></p> <p>Progressive Multifocal Leukoencephalopathy (PML) PML, a rare brain infection, has occurred in patients who have been given TYSABRI. PML usually leads to severe disability or death.</p> <p>The risk of PML appears to increase with treatment duration, especially beyond 2 years.</p> <p>The symptoms of PML may be similar to an MS relapse. Therefore, if you believe your MS is getting worse or if you notice any new symptoms while you are on TYSABRI treatment or for up to 6 months after stopping TYSABRI treatment, it is very important that you speak to your doctor as soon as possible. PML symptoms generally develop more slowly than those associated with an MS relapse (over days or weeks), and may be similar to your MS symptoms.</p> <p>Signs include:</p> <ul style="list-style-type: none"> ○ 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. <p>Management of PML requires immediately stopping TYSABRI treatment.</p> <p>Serious Infections Other serious infections may occur with TYSABRI. Speak to your doctor as soon as possible if you think you have developed a severe, persistent infection, for example a persistent fever.</p> <p>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.</p> <p>You can also report side effects directly via the national reporting system https://medicinesauthority.gov.mt/adrportal. By</p>
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<ul style="list-style-type: none"> • You should not be treated with TYSABRI if you have a serious problem with your immune system • You should not take any other long-term medicines for your multiple sclerosis while receiving TYSABRI 	<p>reporting side affects you can help provide more information on the safety of this medicine.</p> <p><u>Malta Medicines Authority approval date:</u> <u>10/07/2025.</u></p>
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