

# **TYSABRI<sup>®</sup>** **PATIENT** **ALERT** **CARD**

April 2016  
TY-PAN-0687c(1)



**TYSABRI**  
(natalizumab)

**This alert card contains important safety information that you need to be aware of before, during and after stopping treatment with TYSABRI.**

- 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 for 6 months after the last dose of TYSABRI, since side effects may occur even after you 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.



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**Reporting of side effects**

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. 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 Yellow Card Scheme at: **[www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)** (UK), or if in Ireland, via HPRa Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2  
Tel: +353 1 6764971; Fax: +353 1 6712517  
Website: **[www.hpra.ie](http://www.hpra.ie)**; E-mail: **[medsafety@hpra.ie](mailto:medsafety@hpra.ie)**.  
By reporting side effects you can help provide more information on the safety of this medicine.

**Patient's Name:** \_\_\_\_\_

**Doctor's Name:** \_\_\_\_\_

**Doctor's Phone:** \_\_\_\_\_

**Date TYSABRI Started:** \_\_\_\_\_

**Prior to treatment with TYSABRI**

- 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.

**During Treatment with TYSABRI**

**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.

The risk of PML appears to increase with treatment duration, especially beyond 2 years.

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.

Signs Include:

- Changes in mental ability and concentration,
- Behavioural changes,
- Weakness on one side of the body,
- Vision problems,
- New neurological symptoms that are unusual for you.

Management of PML requires withdrawal or removal of TYSABRI from the blood, usually by 'plasma exchange'. In patients with PML a severe inflammatory reaction known as IRIS is likely to occur within days to a few weeks after treatment for PML (and removal of TYSABRI). IRIS may lead to a variety of symptoms including worsening of brain (neurological) function.

**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.

