

Treatments for MS:

Tysabri® (natalizumab)

There is a range of disease modifying therapies approved for people with MS in Australia. These therapies, also called immunotherapies, work to reduce disease activity in the central nervous system and reduce the frequency and severity of relapses in people with MS.

What is Tysabri® and how does it work?

The active ingredient of Tysabri® is natalizumab. Natalizumab is a humanised monoclonal antibody which locks onto certain immune cells, called T-cells. Once the natalizumab is attached to the T-Cells, they cannot cross the blood brain barrier to attack the myelin or nerves. Natalizumab belongs to a family of medications called selective adhesion molecule inhibitors.

Clinical trials¹ found that Tysabri® has a significant beneficial effect in people with relapsing-remitting multiple sclerosis (RRMS) by reducing the accumulation of permanent physical disability, exacerbation frequency and disease activity measured by gadolinium-enhanced lesions on brain magnetic resonance images (MRI).

How is Tysabri® administered?

Tysabri® is infused intravenously (into a vein) once every twenty eight days usually at a hospital i.e. as an outpatient (which may take a few hours). A nurse or other qualified health professional will monitor you before, during and after your infusion.

What are the possible side effects of Tysabri?

Common side effects of Tysabri® include urinary tract infections, sore throat, runny or blocked nose, headaches, dizziness, shivering, rash (hives), nausea, vomiting, joint pain, tiredness and fever.

Progressive Multifocal Leukoencephalopathy (PML) can be associated with taking Tysabri®. PML is a life threatening brain infection caused by the JC virus which manifests in people whose immune system has been suppressed. PML has also been associated with other immunosuppressive medications for MS.

People who are positive for JC virus on antibody testing, have previously received immunosuppression and who have received Tysabri® for a longer duration (especially over two years) are more at risk of developing PML. Some of the symptoms of PML are similar to MS. Your neurologist will assess the risks and the expected benefit of treatment with Tysabri® prior to starting therapy and over the course of treatment.

Women who are pregnant, planning pregnancy or breastfeeding should seek advice from their doctor.

How much does Tysabri® cost?

Tysabri® has been approved by the Therapeutic Goods Administration (TGA) and is listed on the Pharmaceutical Benefits Scheme. Please consult your neurologist to see if Tysabri® is the right treatment for you.

In August 2019, the Pharmaceutical Benefits Advisory Committee (PBAC) recommended the removal of the age restriction from the PBS listing of natalizumab (Tysabri®) to permit its use in paediatric patients with RRMS. Listing on the PBS (from 1/11/19) was announced by the Australian Government on 28/10/19.

As Tysabri® has specific patient management requirements, only neurologists are able to initiate treatment. Your neurologist will need to obtain a special authority (section 100 – ‘Highly Specialised Drugs Program’) to prescribe you with the medication. There are a number of criteria you are required to meet before your neurologist obtains authority to write this prescription.

For details of the criteria required to receive a prescription for Tysabri® treatment through the PBS, please visit the official PBS website at: <http://www.pbs.gov.au/medicine/item/9505G-9624M>

You will need to click on the red **Authority Required (STREAMLINED)** link.

If you are eligible for medications through the PBS, you will need to pay a contribution fee each time your prescription is dispensed. The Federal Government pays for the remaining cost. The amount of the contribution fee depends upon whether or not you have a pension or concession card. The amount of this fee is set each year by the Federal Government.

Further information about the PBS, your entitlements and details regarding the PBS safety net (which protects patients and their families requiring a large number of PBS items) is available through the Medicare Australia website at: www.medicare.gov.au As an infused medication for MS, Tysabri® does not come in a pre-prepared dose. A pharmacist or nurse needs to prepare an individual dose for every person being treated at their clinic. Please check with your clinic about any fees for preparing your dose or for clinic admission.

If you are not eligible for Tysabri® through the PBS, for example you are a visitor from overseas, your neurologist may write a private prescription. In this instance you will have to pay the full cost to the pharmacy that dispenses your medication. The cost is likely to be over \$2000 per month. You will need to request a quote from your pharmacist for the price of any medication which is not subsidised by the PBS.

General information

Generally the clinic where you have your Tysabri® infused will take care of your prescription and order the medication for you. If you do need to get Tysabri® dispensed at your local pharmacy please remember they will need to place an order and have stock delivered especially for you. It is therefore important to give your pharmacist notice to organise the medication.

Tysabri® needs to be kept between 2-8°C. If the outside temperature is warm, it is a good idea to take your medication home in an ice cooler. Your pharmacist may be able to assist with this.

In Australia, Tysabri® is supplied by:

Biogen Australia Pty Ltd

Level 3

123 Epping Road

North Ryde

NSW 2113

Ph: 02 8875 3900

For more information on MS and other MS treatments

- Speak to your neurologist about what treatment best suits your individual circumstances.
 - MS Nurses can also provide information, training and ongoing support in managing your immunotherapy.
 - For information about MS, MS treatment and to find contact details for your state MS organization visit www.msaustralia.org.au
 - MS Research Australia provides information on the latest research and clinical trials at www.msra.org.au
-

References:

1. Tysabri® Consumer Medicine Information, April 2019

<http://www.pbs.gov.au/pbs/home> (search for natalizumab) or visit: <https://bit.ly/2PgIivc>

Note:

MS Australia does not recommend any specific disease-modifying treatment for people living with MS. Decisions about any treatments, taking into consideration the potential benefits and side effects for each individual's circumstances, should be made in careful consultation with the person's neurologist.

The information supplied in this document is collated from material provided on the PBS website, the relevant pharmaceutical company and MS Research Australia.