TYSABRI®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

1. Why am I using TYSABRI?

TYSABRI contains the active ingredient natalizumab. TYSABRI is used to treat relapsing remitting Multiple Sclerosis (MS).

For more information, see Section 1. Why am I using TYSABRI? in the full CMI.

2. What should I know before I use TYSABRI?

Do not use if you have ever had an allergic reaction to Tysabri or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use TYSABRI? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TYSABRI and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use TYSABRI?

- The recommended dose of TYSABRI is 300 mg given once every 4 weeks.
- TYSABRI will be prepared and given to you by a doctor or nurse.

More instructions can be found in Section 4. How do I use TYSABRI? in the full CMI.

5. What should I know while using TYSABRI?

Things you should do	• Remind any doctor, dentist, nurse or pharmacist you visit that you are using Tysabri. • Call your doctor straight away if you or your partner or caregiver notice any new or worsening medical problems (fever or infection, new or sudden change in your thinking, eyesight, balance or strength)
Things you should not do	• Do not stop using this medicine without checking with your doctor.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how TYSABRI affects you. • TYSABRI may cause dizziness in some people.
Drinking alcohol	• Tell your doctor if you drink alcohol.
Looking after your medicine	• Keep TYSABRI in the refrigerator at 2°C to 8°C. • TYSABRI must not be frozen. • Keep TYSABRI in the pack until it is time to use it.

For more information, see Section 5. What should I know while using TYSABRI? in the full CMI.

6. Are there any side effects?

Common side effects include: sore throat, runny nose, nausea or vomiting, pain or stinging when passing urine, shivering, itch, headache, dizziness, tiredness, joint pain or fever.

Serious side effects include: infections, jaundice, anaemia, allergy or infection in the brain.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

WARNING: TYSABRI may increase your chance of getting a rare viral brain infection called progressive multifocal leukoencephalopathy (PML) that may lead to death or severe disability. Your doctor will perform tests to assess your risk of getting PML before giving you TYSABRI. You should also be closely monitored for signs and symptoms of PML while you are taking TYSABRI.

TYSABRI (tie-SA-bree)

Active ingredient(s): *Natalizumab* (nat-ah-li-zoo-mab)

Consumer Medicine Information (CMI)

This leaflet provides important information about using TYSABRI. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using TYSABRI.**

Where to find information in this leaflet:

1. Why am I using TYSABRI?
2. What should I know before I use TYSABRI?
3. What if I am taking other medicines?
4. How do I use TYSABRI?
5. What should I know while using TYSABRI?
6. Are there any side effects?
7. Product details

1. Why am I using TYSABRI?

TYSABRI contains the active ingredient natalizumab. TYSABRI is a type of protein used to treat relapsing remitting Multiple Sclerosis (MS).

The cause of MS is not yet known. MS affects the brain and spinal cord. In MS, the body's immune system reacts against its own myelin (the 'insulation' surrounding nerve fibres). In relapsing remitting MS, people have 'exacerbations' from time to time (e.g. blurred vision, weakness in the legs or arms, or loss of control of bowel or bladder function).

These are followed by periods of recovery. Recovery may be complete or incomplete. If it is incomplete there is 'progression of disability'.

TYSABRI decreases the inflammation in your brain that is caused by Multiple Sclerosis (MS) and thereby reduces nerve damage.

TYSABRI works by binding to white blood cells and preventing them from moving into the brain and spinal cord where they cause inflammation, an important part of the MS disease process.

TYSABRI slows down the progression of physical disability in people with relapsing remitting MS and decreases the number of flare-ups (relapses). Some people feel better when they start to take TYSABRI. However, TYSABRI cannot repair damage that has already been caused by MS.

When you start on TYSABRI you might not notice any improvement, but TYSABRI may be working to help prevent your MS from becoming worse.

TYSABRI has not been tested in clinical trials in people with MS who are 65 years and over. TYSABRI has not been studied in patients with chronic progressive MS.

Your doctor, however, may prescribe TYSABRI for another purpose.

Ask your doctor if you have any questions about why it has been prescribed for you.

There is not enough information to recommend this medicine for children or adolescents under 18 years of age or elderly 65 years and over.

2. What should I know before I use TYSABRI?

Warnings

Do not use TYSABRI if you:

- are allergic to natalizumab, or any of the ingredients listed at the end of this leaflet.
- are allergic to any other proteins that are of mouse origin.

  Always check the ingredients to make sure you can use this medicine.

  Symptoms of allergic reactions may include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin.
- have or have had PML (progressive multifocal leukoencephalopathy). PML is a rare viral infection of the brain.
- have suppressed immune function, e.g. due to:
  - a medical condition, such as HIV-AIDS, organ transplant or cancer
  - medicines that affect the immune system.
- are taking medicines that modify the activity of the immune system e.g. an interferon or glatiramer acetate.

TYSABRI must not be used after the expiry date, if there are particles in the solution, or if it is discoloured or cloudy.

If you are not sure whether you should use this medicine, talk to your doctor, nurse or pharmacist.

Check with your doctor if you have or have had:

- allergies to any other medicines, foods, preservatives or dyes

- an infusion or injection reaction with any other medicine
- liver problems
- previous treatment with TYSABRI.

You will need a recent brain scan (MRI) (within 3 months) before you start treatment with TYSABRI.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Your doctor will discuss the risks and benefits of using TYSABRI if you are pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

TYSABRI passes into the breast milk. Your doctor will discuss the risks and benefits of using it if you are breast-feeding or planning to breast-feed.

Patient card

A patient card is available, which summarises the most important information from this leaflet. A patient card is available via either scanning the QR code or clicking the link below.

https://tys-au.biogenalertcards.com/

Refer to this leaflet and the patient card during treatment and for at least 6 months after your last dose, as side effects can occur after you have stopped treatment.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

In particular, tell your doctor if you are being treated or have previously been treated with any medicine that affects immune function.

Examples of such medicines may include:

- medicines used for autoimmune diseases or after organ transplant, e.g. azathioprine
- cancer drugs, such as mitoxantrone
- steroids, e.g. for asthma, arthritis or skin disease.

You may not be able to take some medicines that affect your immune system at the same time as having treatment with TYSABRI.

- There are many medicines that can affect immune function. It is a good idea to keep a list of your medicines and take it with you when you go to your doctor or treatment centre.

Check with your doctor, nurse or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect TYSABRI.

4. How do I use TYSABRI?

How much to use

- The recommended dose of TYSABRI is 300 mg given once every 4 weeks.
- **Follow all directions given to you by your doctor, nurse or pharmacist carefully.**

  They may differ from the information contained in this leaflet.

When to use TYSABRI

- TYSABRI is given once every 4 weeks.

How to use TYSABRI

- TYSABRI will be prepared and given to you by a doctor or nurse.
- TYSABRI for infusion will be diluted before it is given to you. It is given as a drip through a needle placed into a vein (IV infusion), usually in your arm. This takes about 1 hour.
- TYSABRI injection in prefilled syringes requires no preparation. It is given as two injections just under the skin of your thigh, abdomen or upper arm.
- A few patients have had an allergic reaction to TYSABRI. Your doctor or nurse will check for allergic reactions during the infusion or injection and for 1 hour afterwards.
- Infusion with TYSABRI should start as soon as possible after the medicine has been diluted. If not used immediately, the solution must be stored at 2°C to 8°C and infused within 72 hours of dilution.
- The prefilled syringes can be kept in their original packaging at room temperature for a combined total period of up to 24 hours, including the time to allow warming to room temperature for administration. If necessary, the prefilled syringes may be returned to the refrigerator. The total time at room temperature must not exceed 24 hours. Do not use external heat sources, such as hot water, to warm the prefilled syringes.

The positive effects of TYSABRI may not be seen immediately.

They occur with long-term treatment. It is important to continue treatment with TYSABRI unless your doctor tells you to stop.

Do not interrupt your treatment, especially during the first few months. Patients who received up to 3 doses of

TYSABRI followed by a gap in treatment of 3 months or more, were more likely to have an allergic reaction when restarting treatment.

Your doctor will discuss with you the benefits and risks of continuing treatment after 2 years.

If you forget to use TYSABRI

TYSABRI is given once every 4 weeks. If you miss one of your treatments, you should have it as soon as possible, unless your doctor has told you otherwise. Then resume your regular monthly schedule.

If you use too much TYSABRI

As TYSABRI is given to you under the supervision of a doctor or nurse, it is unlikely that you will receive too much.

Nevertheless, if you think that you have been given too much TYSABRI, you may need urgent medical attention.

You should immediately:

- phone the Australian Poisons Information Centre (**by calling 13 11 26**), or the New Zealand National Poisons Information Centre (**by calling 0800 POISON or 0800 764 766**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using TYSABRI?

Things you should do

Call your doctor straight away if you:

- if you notice any new or worsening medical problems (fever or infection, new or sudden change in your thinking, eyesight, balance or strength) that have lasted several days.
- Tell your partner or caregiver about your treatment.

Ask them to tell your doctor immediately if they notice any changes in you, such as a new or sudden change in your personality, thinking abilities or any unusual behaviour.

When possible, encourage your partner or caregiver to go with you to see your doctor and to the centre for your treatments.

PML and TYSABRI

TYSABRI increases your chance of getting a rare viral brain infection called progressive multifocal leukoencephalopathy (PML) that can cause severe disability or be life-threatening.

Your chance of getting PML increases if you have been exposed to John Cunningham Virus (JCV). Approximately half of all people have been exposed to JCV. JCV is a common virus that is harmless in most people but can cause PML in people who have weakened immune systems, such as people taking TYSABRI. Most people have been exposed to JCV without knowing it or having any symptoms. This exposure usually happens in childhood.

Your doctor should test your blood to check if you have antibodies to the JC virus before treatment and periodically during treatment.

The risk of developing PML whilst on TYSABRI is higher:

- If you have antibodies to the JC virus in your blood. These antibodies are a sign that you have been infected by JC virus.
- The longer you are on treatment, especially if you have been on treatment for more than two years.
- If you have previously taken a medicine called an immunosuppressant. These medicines reduce the activity of your body's immune system.

Your risk of getting PML is greatest if you have all 3 risk factors listed above.

If you have not previously been treated with an immunosuppressant and you have received TYSABRI for two years or longer, the level of your anti-JC virus antibody test results may help your doctor assess your risk of getting PML. Your doctor may repeat the test regularly to check if anything has changed:

- if you do not have antibodies to the JC virus in your blood

  OR

- if you have been treated for more than 2 years and you have a lower level of JCV antibodies in your blood.

You should discuss with your doctor if TYSABRI is the most suitable treatment for you before you start treatment and when you have been taking TYSABRI for more than two years if you have antibodies to the JC virus in your blood.

Some of the symptoms of PML are similar to MS. If you believe your MS is getting worse or if you notice new symptoms while you are on TYSABRI treatment or for up to 6 months after stopping TYSABRI, it is important to speak to your doctor as soon as possible.

If you have new symptoms, or an infection, that last or worsen over several days, contact your doctor before you go for your next treatment.

In some cases, you may not be able to have your treatment without first seeing your doctor. They will be able to tell you if this is necessary.

If your doctor suspects PML, they will want you to stop treatment with TYSABRI either permanently or until they can confirm it is not PML.

Management of patients with PML may require removal of TYSABRI from the blood, usually by plasma exchange. This may lead to further serious complications, including worsening of brain (neurological) function. Your doctor will monitor you for this.

Keep all your doctor's appointments so that your progress can be checked.

Your doctor will need to see you 3 months after your first treatment, 6 months after your first treatment and every 6 months after that. They may also need to see you between

routine check-ups if you have had liver problems or in the case of some side effects. Your doctor may also perform regular brain scans (MRI) to check the progress of your MS and if you have a higher chance of getting PML.

If you become pregnant while on treatment with TYSABRI, immediately tell your doctor.

Your doctor will discuss the risks and benefits of being given TYSABRI if you become pregnant.

Tell any other doctors, dentists and pharmacists who treat you that you are using this medicine.

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are using or have used TYSABRI. Tell your doctor if you are going to be vaccinated.

TYSABRI may have effects for about 12 weeks after the last dose. Any new medicine you start during this time might be affected by your previous treatment with TYSABRI.

If you are about to have any blood tests, tell your doctor that you are using or have used TYSABRI.

It may interfere with the results of some tests.

Things you should not do

- Do not stop using this medicine without checking with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how TYSABRI affects you.

There are no studies of the effect of TYSABRI on your ability to drive or to operate machinery but TYSABRI may cause dizziness in some people. Make sure you know how you react to TYSABRI before you do anything that could be dangerous if you are dizzy.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- **Keep TYSABRI in the pack until it is time to use it.**
- This medicine will not keep as well if taken out of the packaging.
- **Keep TYSABRI in the refrigerator at 2°C to 8°C.**
- **TYSABRI must not be frozen.** Do not place in the freezer or freezing compartment of a refrigerator.

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

Each vial or prefilled syringe of TYSABRI should be used once only. The doctor or nurse will discard any unused portion.

6. Are there any side effects?

TYSABRI helps most people with MS but it may have unwanted effects in a few people. All medicines have side effects. Sometimes they are serious, most of the time they are not.

See the information below and, if you need to, ask your doctor, nurse or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Respiratory-related: • sore throat • runny or blocked nose **Digestion system-related:** • feeling sick (nausea) • being sick (vomiting) **Urine system-related:** • pain or stinging when passing urine **Nervous system-related:** • headache • dizziness • tiredness **Non-specific effect on the body:** • shivering • itchy rash (hives) • joint pain • fever	**Speak to your doctor if you have any of these less serious side effects and they worry you.** **If any of these side effects persist or worsen, talk to your doctor as they may also be due to an infection or allergic reaction.**

Serious side effects

Serious side effects	What to do
Infection-related: • unexplained fever, severe diarrhoea, prolonged dizziness, headache or stiff neck, weight loss, listlessness, impaired vision, pain or redness of the eye(s) **Liver-related:** • yellowing of the skin or eyes (also called jaundice) **Blood-related:**	**Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.** **Serious side effects are rare.**

Serious side effects	What to do
• tiredness, headaches, shortness of breath when exercising, dizziness, or looking pale, which may be signs of severe anaemia due to a decrease in red blood cells. **Allergic reaction-related:** • itchy rash or hives • swelling of your face, lips, tongue or other parts of the body • shortness of breath, wheezing, difficulty breathing, chest pain or discomfort. These can be signs of very serious side effects. If you have them, you may have had a serious allergic reaction to TYSABRI. **Serious infection of the brain related:** • psychological or intellectual changes such as changes in personality and behaviour, difficulty performing mental tasks, confusion, delirium or loss of consciousness, seizures (fits), headache, nausea / vomiting, stiff neck, extreme sensitivity to bright light, fever, rash.	

There have been reports of a rare brain infection called PML (progressive multifocal leukoencephalopathy) occurring in patients who have been given TYSABRI.

PML is a serious condition and can cause severe disability or be life-threatening.

Some of the symptoms of PML are similar to MS, so it is important that you speak to your doctor as soon as possible if you notice any new symptoms, or if your MS gets worse (see the 'PML and TYSABRI' section of this CMI).

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What TYSABRI contains

Each vial of TYSABRI for infusion contains 300 mg natalizumab in 15 mL of solution.

Each prefilled syringe of TYSABRI for subcutaneous injection contains 150 mg natalizumab in 1 mL of solution.

Active ingredient (main ingredient)	Natalizumab
Other ingredients (inactive ingredients)	sodium chloride monobasic sodium phosphate monohydrate dibasic sodium phosphate heptahydrate polysorbate 80 water for injections.
Potential allergens	None

Do not take this medicine if you are allergic to any of these ingredients.

TYSABRI does not contain any preservative.

What TYSABRI looks like

Each pack of TYSABRI for infusion contains one vial of TYSABRI. TYSABRI for infusion is a colourless, clear to slightly opalescent, concentrated solution for infusion.

Each pack of TYSABRI for subcutaneous injection contains two prefilled syringes of TYSABRI.

TYSABRI for subcutaneous injection is a colourless to slightly yellow, slightly opalescent to opalescent solution for injection.

Australian Register Number:

AUST R 112372 (concentrated solution for infusion)

AUST R 353845 (solution for subcutaneous injection)

Further information

You can obtain more information from your doctor, pharmacist or the MS Society in your State, or by telephoning 1800 852 289 in Australia or 0800 852 289 in NZ.

Who distributes TYSABRI

TYSABRI is supplied in Australia by:

Biogen Australia Pty Ltd

ABN 30 095 760 115

Level 4, 2 Banfield Road

Macquarie Park NSW 2113

Australia

TYSABRI is supplied in New Zealand by:

Biogen NZ Biopharma Limited

Auckland, New Zealand

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