TYSABRI®

(tie-SA-bree)

Natalizumab (nat-ah-li-zoo-mab)

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about TYSABRI Concentrated Injection Solution.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the benefits TYSABRI is expected to have for you against the risks of using it.

Your doctor will discuss the benefits and risks of using TYSABRI with you before you start treatment.

If you do not understand something your doctor has told you, please ask your doctor again.

When you understand the benefits and risks, your doctor will ask you to sign a consent form. They will give you a Patient Alert Card to keep with you, which summarises the most important information from this leaflet.

If you have any questions about using this medicine, ask your doctor, nurse or pharmacist.

You can also telephone the MS ALLIANCE Helpline on 1800 286 639 in Australia or 0800 286 639 in New Zealand (NZ) for additional assistance on using TYSABRI.

Keep this leaflet and the Patient Alert Card with you during treatment and for at least 6 months after your last dose, as side effects can occur after you have stopped treatment.

What TYSABRI is used for

TYSABRI is 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 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.

How it works

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 contains the active ingredient natalizumab (rmc). Natalizumab is a type of protein. It decreases the inflammation in your brain that is caused by 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.

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.

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

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

Before you are given TYSABRI

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

When you must not be given it

Do not use TYSABRI if you have had an allergic reaction to:

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

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.

Do not use TYSABRI if you:

1. **Have or have had PML (progressive multifocal leukoencephalopathy).**

   PML is a rare viral infection of the brain.

2. **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.

Do not use TYSABRI at the same time as 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.

Before you are given it

Tell your doctor if you have or have had:

- allergies to any other medicines, foods, preservatives or dyes
- an infusion reaction with any other medicine
- liver problems
- previous treatment with TYSABRI.

Tell 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.

Tell your doctor if you are breast-feeding or plan to breast-feed.

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

If you have not told your doctor about any of the above, tell them before you use TYSABRI.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any prescribed by other doctors or that you buy without a prescription from a 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 infusion centre.

Ask your doctor, nurse or pharmacist if you have any questions about medicines to be careful with or avoid while using TYSABRI.

How TYSABRI is given

Follow all directions given to you by your doctor, nurse or pharmacist carefully.

They may differ from the information contained in this leaflet.

How much to use

The recommended dose of TYSABRI is 300 mg given once every 4 weeks.

How to use it

TYSABRI will be prepared and given to you by a doctor or nurse.

TYSABRI 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.

A few patients have had an allergic reaction to TYSABRI. Your doctor or nurse will check for allergic reactions during the infusion 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 8 hours of dilution.

When it is given

TYSABRI is given by infusion once every 4 weeks.

How long to use it

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 it

If you miss an infusion, you should have it as soon as possible, unless your doctor has told you otherwise. Then resume your regular monthly schedule.

If you take too much (overdose)

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

Nevertheless, immediately tell your doctor or nurse, or ring the Australian Poisons Information Centre (telephone 131 126), or the New Zealand National Poisons Information Centre (telephone 0800 POISON or 0800 764 766), if you think you or anyone else has been given too much TYSABRI. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are being given TYSABRI

Things you must do

Speak to your doctor as soon as possible 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 infusion 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 infusion.

In some cases, you may not be able to have your infusion 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 must not do

Do not stop using TYSABRI without checking with your doctor.

Things to be careful of

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.

Side effects

Tell your doctor as soon as possible if you do not feel well while using TYSABRI.

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.

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you:

- pain or stinging when passing urine
- sore throat, runny or blocked up nose
- shivering
- itchy rash (hives)
- headache
- dizziness
- feeling sick (nausea)
- being sick (vomiting)
- joint pain
- fever
- tiredness.

The above list includes the more common side effects of TYSABRI.

If any of these persist or worsen, talk to your doctor as they may also be due to an infection or allergic reaction.

Tell your doctor as soon as possible if you notice any of the following:

- signs of an infection, e.g. unexplained fever, severe diarrhoea, prolonged dizziness, headache or stiff neck, weight loss, listlessness, impaired vision, pain or redness of the eye(s)
- yellowing of the skin or eyes (also called jaundice), signs of a possible liver problem
- 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
- easy bruising, small scattered red, pink or purple spots on your skin, heavier than usual menstrual periods, bleeding from gums or nose that is new or takes longer to stop, bleeding from cuts that is hard to stop. These may be due to a decrease in platelets in your blood.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

Speak to your doctor or nurse immediately if you notice any of the following during or after your infusion:

- 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. You may need urgent medical attention or hospitalisation. Serious side effects are rare.

Speak to your doctor or nurse immediately if you notice any of the following:

- symptoms caused by a serious infection of the brain that may include 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.

You may need urgent medical attention or hospitalisation. These side effects are uncommon.

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 if you notice anything else that is making you feel unwell.

Other side effects, which are not listed, may occur in some patients.

Ask your doctor to answer any questions you may have.

After receiving TYSABRI

Storage

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.

Do not store TYSABRI or any other medicine in the bathroom or near a sink. Do not leave it on a windowsill or in the car.

Heat and dampness can destroy some medicines.

TYSABRI must not be frozen.

Do not place in the freezer or freezing compartment of a refrigerator.

Keep TYSABRI where children cannot reach it.

Disposal

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

Product description

What it looks like

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

Australian Register Number:

AUST R 112372

Ingredients

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

TYSABRI also contains:

- sodium chloride
- monobasic sodium phosphate monohydrate
- dibasic sodium phosphate heptahydrate
- polysorbate 80
- water for injections.

TYSABRI does not contain any preservative.

Sponsor

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

msalliance

For additional patient support with treatment, contact:

Australia - 1800 286 639

New Zealand - 0800 286 639

The Patient Support Program is not authorised or approved by the Australian regulator of medicines, the TGA or the New Zealand regulator of medicines, Medsafe.

This leaflet was prepared in November 2020.