

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 anything 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 an 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.

Keep this leaflet and the Patient Alert Card with you during treatment and for at least 6 months after your last dose.

Side effects can occur after you have stopped treatment.

What it is used for

What TYSABRI is used for

TYSABRI is used to treat relapsing remitting Multiple Sclerosis (MS).

TYSABRI is available only with a doctor's prescription. Only a neurologist can start you on treatment and supervise your ongoing treatment.

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

Your doctor may have prescribed TYSABRI for another reason.

TYSABRI is to be given only to the person for whom it has been prescribed.

TYSABRI has not been tested in clinical trials in people with MS who are below 18 years of age or 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 still be working to help prevent your MS from becoming worse.

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

TYSABRI contains the active ingredient natalizumab (rnc). 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.

Before you are given it

You will need a recent, within 3 months, brain scan (MRI) 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 leucoencephalopathy).**
PML is a rare 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 if you are being treated with 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 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.

Like many medicines, it is not recommended to use TYSABRI during pregnancy. 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 can pass into breast milk.

If you have not told your doctor about any of the above, tell them before you start using 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 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 mitozantrone
- 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 it 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.

Not interrupting your treatment with TYSABRI is important, especially during the first four months. This is because 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.

There is no information from clinical studies on the safety and effectiveness of TYSABRI beyond 2 years of 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 using it

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 you if they notice any changes in you, such as intellectual or psychological changes or 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.

TYSABRI increases your chance of getting a rare brain infection called progressive multifocal leukoencephalopathy (PML) that can cause severe disability or even death. 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 TY SABRI. Most people have been exposed to JCV without knowing it or having any symptoms. This exposure usually happens in childhood.

The risk of developing PML whilst on TY SABRI is higher:

- the longer you are on treatment, especially if you have been on treatment for more than two years. It is not known if the chance of getting PML continues to rise, remains the same, or falls after you have been on TY SABRI for more than three years.
- if you have previously taken a medicine called an immunosuppressant. These medicines reduce the activity of your body's immune system.
- if you have antibodies to the JC virus in your blood. These antibodies are a sign that you have been infected by JC virus.

Your doctor may test your blood to check if you have antibodies to the JC virus before treatment and periodically during treatment. The risk of PML is higher in patients who have antibodies to JC virus and lower in patients who do not have antibodies to JC virus.

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

You should discuss with your doctor if TY SABRI is the most suitable treatment for you before you start treatment and when you have been taking TY SABRI for more than two years.

Some of the symptoms of PML are similar to MS. If your doctor suspects PML, they will want you to stop treatment with TY SABRI until they can confirm it is not PML.

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.

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 in the case of some side effects.

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

It is likely that your doctor will consider stopping TY SABRI.

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 TY SABRI. 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 TY SABRI.

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

It may interfere with the results of some tests.

Things you must not do

Do not stop using TY SABRI without checking with your doctor.

Things to be careful of

TYSABRI is not expected to have an effect on your ability to drive or to operate machinery but it may cause dizziness in some people. Make sure you know how you react to TY SABRI 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 TY SABRI.

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 TY SABRI. **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 or listlessness
- psychological or intellectual changes, e.g. confusion, personality changes, unusual behaviour or difficulty performing mental tasks
- yellowing of the skin or eyes (also called jaundice).

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 are 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. These side effects are rare.

There have been reports of a rare brain infection called PML (progressive multifocal leucoencephalopathy) occurring in patients who have been given TYSABRI. PML is a serious condition and can cause severe disability or even death. 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.

It is also important to tell your partner or caregiver about your treatment, and ask them to go with you to see your doctor and to the infusion centre, when possible. They may notice changes in your personality, thinking abilities or behaviour before you do.

Management of PML requires removal of TYSABRI from your body. This can lead to further serious complications, including worsening of brain (neurological) function.

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 being given it

Storage

Keep TYSABRI in the pack until it is time to use it.

The 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 phosphate
- sodium chloride
- polysorbate 80
- water for injections.

TYSABRI does not contain:

- lactose
- gluten
- preservatives.

Sponsor

TYSABRI is supplied in Australia by:

Biogen Idec Australia Pty Ltd
ABN 30 095 760 115
Suite 1, Level 5, 123 Epping Road
North Ryde NSW 2113
Australia

TYSABRI is supplied in New Zealand by:

Biogen Idec NZ Limited
Auckland, New Zealand

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