Your Guide to TYSABRI® (Natalizumab)

Subcutaneous injection

This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA

Please ensure that you also read the patient information leaflet that comes with your medicine.

Contents

Understanding TYSABRI®

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Understanding my Tysabri® treatment

What is Tysabri®?

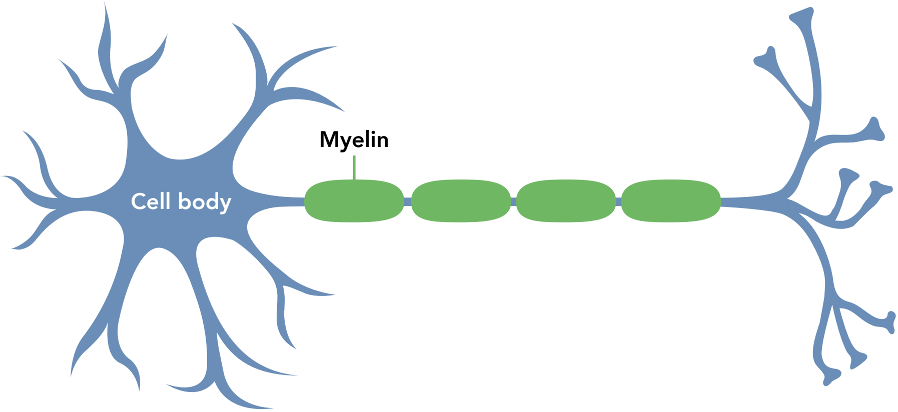
Tysabri® is a treatment for multiple sclerosis (MS) that contains natalizumab. Natalizumab is a type of protein called a monoclonal antibody.

Monoclonal antibodies are similar to the naturally occurring antibodies that our immune systems create to fight infection.

How will Tysabri® be administered?

You will receive Tysabri® as a subcutaneous injection (under the skin from your healthcare provider or as an intravenous infusion at the clinic or infusion centre.

A healthy nerve



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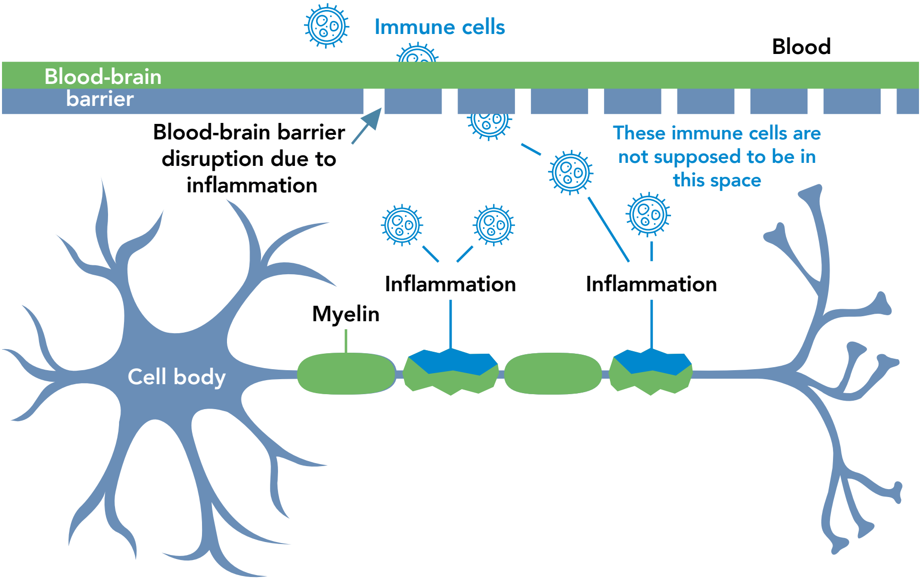
How does Tysabri® work?

Your brain and spinal cord – called your central nervous system or CNS – send messages between your brain and the rest of your body about moving, thinking and using your senses. The CNS is made up of tiny nerves, wrapped up in a fatty layer called myelin. The myelin sheath acts like insulating tape on an electrical cable. The diagram to the left shows part of a healthy nerve.

Effect of MS



Normally, the blood-brain barrier (a border separating circulating blood from the brain) only allows a few immune cells into your CNS. In Multiple sclerosis(MS), once in the brain, immune cells can escape from the blood vessels and damage the myelin around your nerves. This causes inflammation, which allows more immune cells to get into the CNS.

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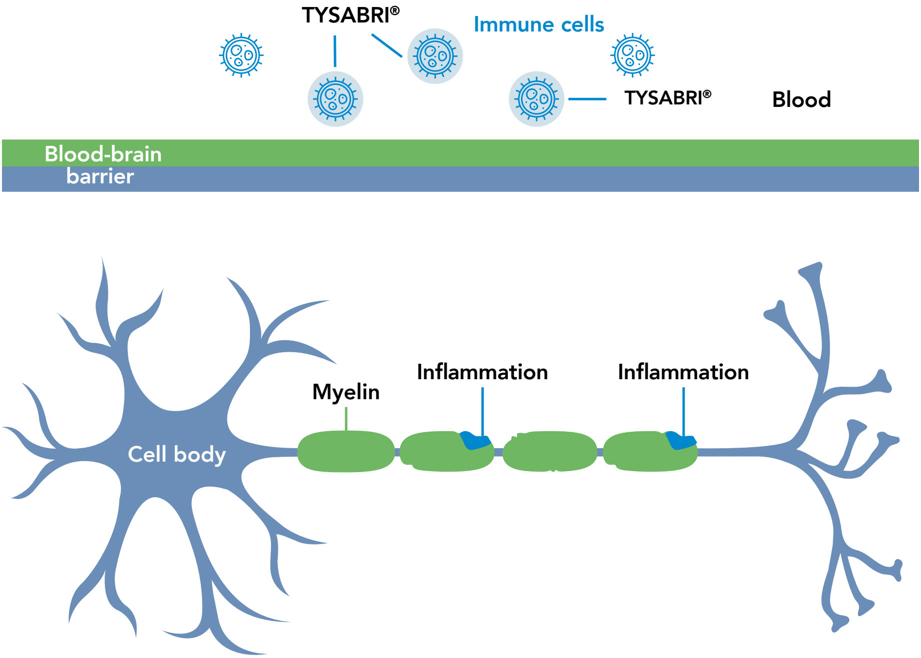
Potential effect of Tysabri®



Tysabri® binds to the immune cells, preventing them from crossing the blood brain barrier and reducing the damage to your nerves. Tysabri® is a reversible treatment. If Tysabri® is stopped, the immune cells will once again be able to cross the blood-brain barrier and the inflammation may return over time. Therefore, it is important that you continue to receive Tysabri® as prescribed by your MS team. Receiving Tysabri® will not impact your future treatment options.

Please note: these diagrams are theoretical and for illustrative purposes only.

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How could Tysabri® help me?

Receiving Tysabri® as prescribed decreases the number of relapses and slows the physical challenges that may arise with MS.

Sometimes the effects of Tysabri® are gradual, so that it's only when you think back over a few months or a year that you notice you are feeling better.

In studies of people with relapsing remitting MS, receiving Tysabri® reduced the number of relapses compared with placebo (dummy treatment).

A study found that in patients with relapsing multiple sclerosis, Tysabri®:

- reduced the risk of progression of disability
- reduced the rate of relapse per year after two years of treatment[2]

Tysabri® also reduced the worsening of disability by around a half and has been shown to reduce disease activity measured by MRI in a study of Tysabri® versus placebo treatment

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Do I have to keep receiving Tysabri®?

Like anyone with a long-term condition, you need to continue receiving your treatments over a long period of time.

You should continue to receive Tysabri® for as long as you and your doctor agree it is the best treatment option for you.

It might help to think of Multiple sclerosis (MS) like an iceberg (as shown in the picture on the next page), with how you feel as the part that is above the surface, while any changes to your brain and spinal cord caused by Multiple sclerosis (MS) are hidden under the surface.

Tysabri® can help to reduce the unseen changes caused by Multiple sclerosis(MS) that are happening under the surface, even when you feel well, and your Multiple sclerosis(MS) seems to be stable.

REMINDER

It is really important to stick with your Tysabri® treatment even when you feel well, because it is preventing inflammation, keeping the changes under the surface at bay

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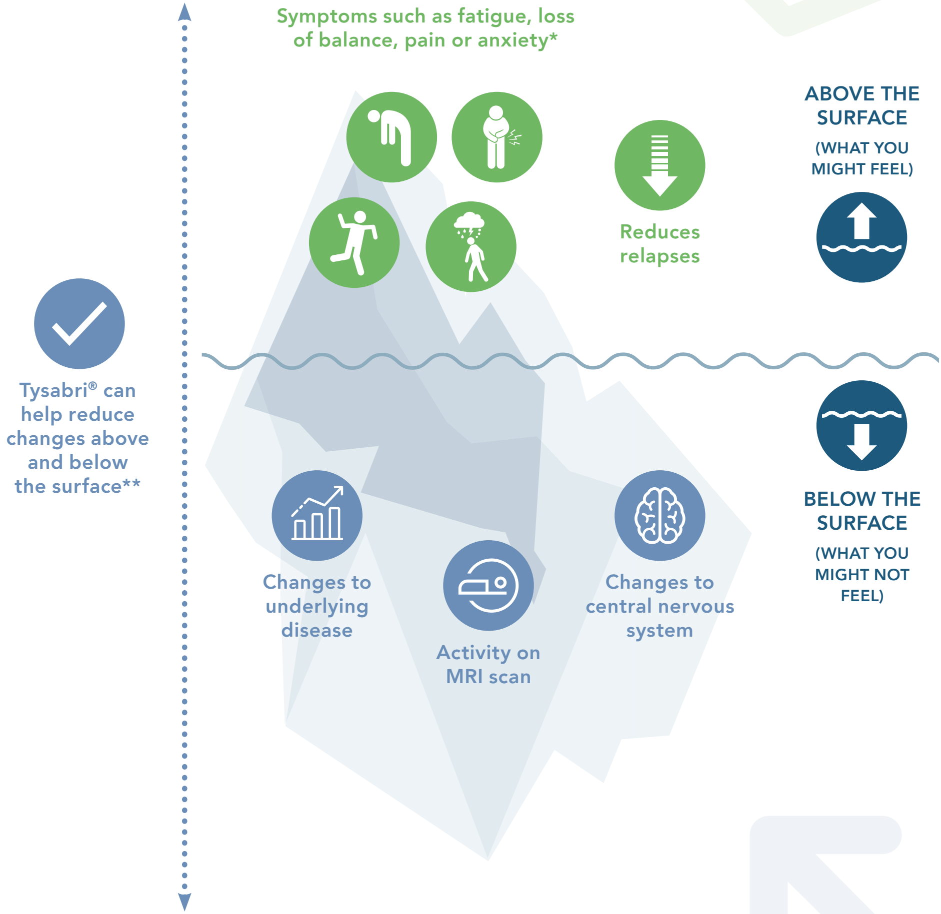

Symptoms such as fatigue, loss of balance, pain or anxiety*

Reduces relapses

ABOVE THE SURFACE

(WHAT YOU MIGHT FEEL)

Tysabri® can help reduce changes above and below the surface**

Changes to underlying disease

Activity on MRI scan

Changes to central nervous system

BELOW THE SURFACE

(WHAT YOU MIGHT NOT FEEL)

*not everyone will experience the symptoms shown.

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Using Tysabri® during pregnancy and breast-feeding

Can I receive Tysabri® if I want to have children?

For more information around family planning, speak with your MS team.

It is considered unlikely that Tysabri® will affect fertility of men or women.

If you are pregnant, breast-feeding or think you may be pregnant you should discuss this with your doctor before starting Tysabri®.

Be sure to tell your doctor immediately if you are pregnant, think you may be pregnant, or if you are planning to become pregnant.

Do not breast-feed whilst using Tysabri®. You should discuss with your doctor whether you choose to breast-feed or to use Tysabri®.

THINGS TO CONSIDER

- Plan your questions: make a list of topics to discuss with your doctor
- List your medicines: make a list of anything you take, including supplements
- Make a list of any conditions or symptoms you have, now or in the past, that the doctor might need to know about

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Can I take other medicines while receiving Tysabri?

Because of the way Tysabri® affects the immune system, you must not receive Tysabri® if you are being treated with other medicines for Multiple sclerosis (MS).

You may not be able to use Tysabri® if you are currently taking or have previously received medicines that affect your immune system.

It is important to let your Multiple sclerosis (MS) team know of any other medicines you are being treated with, even if they are unrelated to your Multiple sclerosis (MS). This includes any medicines prescribed by other doctors or those that you buy without a prescription.

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Administering TYSABRI® Subcutaneous injection

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Understanding how Tysabri® is administered subcutaneously

How can Tysabri® be administered?

Tysabri® can be administered either as a subcutaneous injection from your healthcare provider or as an intravenous infusion at the clinic or infusion centre.[1] This section relates only to subcutaneous administration.

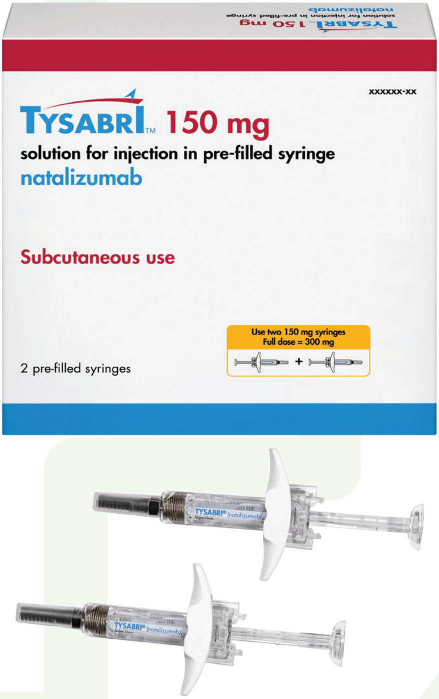
How is Tysabri® administered subcutaneously?

You will receive Tysabri® as an injection under the skin, this is known as a subcutaneous injection, by a healthcare professional, once every four weeks.

You will receive your Tysabri® injection at the hospital or clinic.

What will my injection look like?

Tysabri® is administered via a pre-filled syringe pre-filled syringe. Your healthcare professional will inject you with two syringes in order to give you the full dose.



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What will happen before I have my first injection?

Your doctor will have checked to see if Tysabri® is the right treatment.[1] This may include a blood test to look at your overall health, and to check if you have been exposed to the JC virus.

This virus can increase your probability of developing a rare brain infection called progressive multifocal leukoencephalopathy (PML).

You will be asked to sign a treatment initiation form covering the benefits and risks of treatment.

How can I keep track of my treatment?

Putting appointment dates into your calendar or diary as soon as you get them will help you to remember your appointment dates.

If you find it difficult to remember your appointment dates, talk it over with your doctor or Multiple sclerosis (MS) nurse – they could have ideas to make it easier for you.

THINGS TO CONSIDER

Use a calendar or diary to keep a note of how you have felt since your last Tysabri® injection. This could include improvements in your symptoms, or any new Multiple sclerosis (MS) symptoms or side effects if you have them. Have your notes available for when you have your injection

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What happens when I have my injection?

1. Before you receive your injection you will be asked to complete a pre-injection checklist and a doctor or MS nurse will do some routine checks, and ask you how you have felt since your last injection

2. The doctor or nurse will inject Tysabri® under the skin (subcutaneously), either in the thigh, abdomen, or back of the upper arm. You will receive two injections, one after the other, to receive the full dose of Tysabri®

3. The injection process should only take a few minutes

4. A nurse or doctor will keep an eye on you for around an hour after your injection to look out for signs and symptoms of injection reactions. They will also let you know what to look out for, for yourself. Please follow their guidance

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How can I plan ahead for my injections?

Plan ahead so you're not rushing to get ready for your appointment

Take something to entertain you such as a book, magazine or a tablet computer, in case of any delays, and for after you have received your injection

Make a note of any questions you might have for your Multiple sclerosis (MS) team. Your injection appointment is a good opportunity to ask these

Before the first injection some people find it useful to meet the nurse that will be administering the injection, or visit the clinic, to familiarise themselves with what to expect

Consider having someone else driving you to or from the hospital if this is your first appointment as you may feel dizzy

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What else do I need to know?

You will be given a Patient Alert Card.[1] This includes important safety information. You should carry this with you at all times, in case of an accident or an emergency. You need to show it to any healthcare professional involved in your treatment, not just your doctor.

What if I don't want to continue injections?

Speak to your Multiple sclerosis (MS) team if you have any concerns about your Tysabri® injections.

REMINDER

Thinking about why you are using Tysabri®, and how it will help you manage your Multiple sclerosis (MS) , may help you overcome any concerns you have about

I've missed a dose – what should I do?

It's important that you have your Tysabri® injection as prescribed by your Multiple sclerosis (MS) team to get the most from your treatment. People with Multiple sclerosis (MS) who adhere to their medication as prescribed, have better health, with fewer relapses, than those who don't take their medication as prescribed.[5]

If you miss your usual injection of Tysabri®, make a new appointment to have your injection as soon as you can. You can then continue to receive Tysabri® according to the agreed frequency.

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What if my doctor has prescribed Tysabri® to be administered at a frequency different than approved 4-week dosing inerval?

Although the approved dose of Tysabri® is every 4 weeks, your MS team may extend the time between injections. Always stick to the agreed dosing schedule provided by your Multiple sclerosis (MS) team.

continuing treatment

REMINDER

It is important to have your Tysabri® injections as prescribed, especially in the first few months of treatment. Missing injections in the first few months can increase your risk of having an allergic reaction to Tysabri®

SUGGESTIONS

- ☑ Discuss your Multiple sclerosis (MS) with your doctor, including talking about how soon you could see the effects of Tysabri®
- ☑ Track how you feel each day, so you can look back and see how things have changed
- ☑ Tell your doctor if you have any Multiple sclerosis (MS) symptoms
- ☑ Talk to your Multiple sclerosis (MS) team as soon as you can if you need to change an appointment date

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Remembering my appointments

How can I keep track of my treatment?

Putting appointment dates into your calendar or diary as soon as you get them will help you to remember when they are.

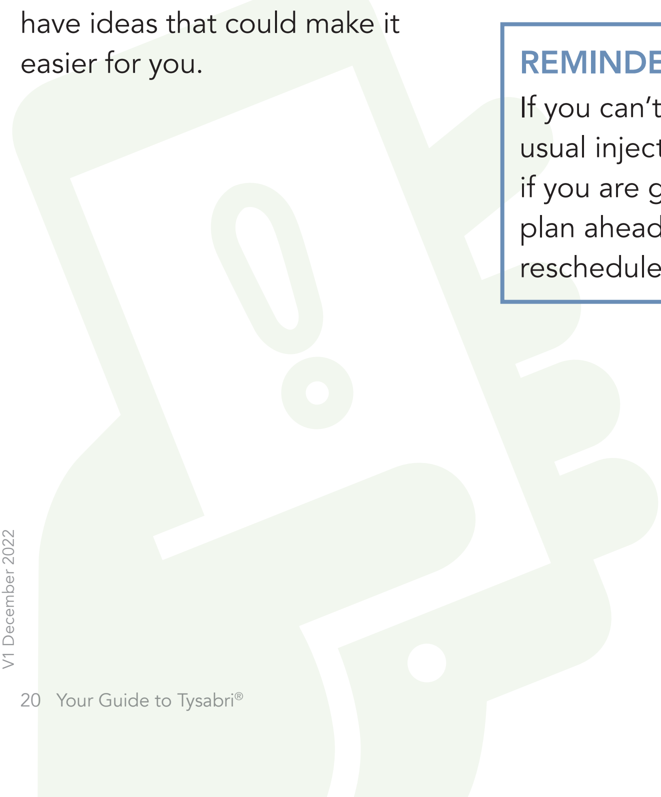
If you find it difficult to remember your appointment dates, talk it over with your doctor or nurse – they should have ideas that could make it easier for you.

THINGS TO CONSIDER

Struggling to get into the habit? Try marking the days in a diary, using stickers on a calendar, setting an alert on your phone, or using a reminder app

REMINDER

If you can't make your usual injection, for example if you are going on holiday, plan ahead with your nurse to reschedule your appointment



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Monitoring my response to TYSABRI®

Monitoring my response to Tysabri®

How can I track my Tysabri® treatment?

You and your Multiple sclerosis (MS) team can collaborate to keep an eye on your general health, and see how you are responding to treatment with Tysabri®.

REMINDER

Make sure you attend any appointments your Multiple sclerosis (MS) team suggest for you - such as regular blood tests, or appointments with a MS nurse or your neurologist

Attending appointments and having regular MRI scans and blood tests will allow your doctor to see how well you are doing.

Results from tests can also pick up any side effects caused by Tysabri® even before you feel the symptoms, helping you and your Multiple sclerosis (MS) team to resolve them.

Let your Multiple sclerosis (MS) team know if you are taking any prescribed or over the counter medicines, herbal preparations or supplements. If you see a doctor or nurse who isn't part of your Multiple sclerosis (MS) team, let them know you are on Tysabri® and show them your Patient Alert Card, as Tysabri® may affect how other medicines work, or have an impact on the results of blood tests.

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Your Patient Alert Card contains important safety information that you need to be aware of before, during and after stopping treatment with Tysabri®. Your card will be given to you by your Multiple sclerosis (MS)team.

If you discontinue Tysabri® for any reason, you will still need to carry your Patient Alert card for six months after stopping treatment. This is because Tysabri® continues to have an effect after the last treatment and side effects may occur even after you have stopped treatment.

REMINDER

Tell your doctor about anything else that you are taking, or have taken recently, including any over the counter medicines or supplements

How often will I see my Multiple sclerosis (MS) team while I am receiving Tysabri®?

How often you meet with your Multiple sclerosis(MS) team will be depend on your situation, typically you will meet with your doctor three months and six months after your first treatment, and then every six months after that. You may also have other routine check-ups and tests in between. You will also see your healthcare provider or nurse when you receive your Tysabri® dose.

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What kinds of tests will I have?

You will have tests before and during treatment, to check your health and your response to Tysabri®. These may vary depending on your medical history and the recommendations from your Multiple sclerosis (MS) team. Not everyone will receive the same tests. Your Multiple sclerosis(MS) team will interpret these tests and communicate any necessary information to you.

Before starting treatment:

MRI scan, usually before starting, or within the first three months

Blood tests to check your general health

Your doctor may test your blood to check if you have antibodies to the JC virus before you start treatment with Tysabri®

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During treatment:

Blood tests to check your liver

Separate blood tests to see your JC virus status – exposure to the virus can increase your probability of developing a rare brain infection called PML (progressive multifocal leukoencephalopathy). The blood tests required will depend on your JCV status and will therefore vary for different people

Periodic MRI scans to:

- See if there are any Multiple sclerosis (MS) changes to your nerves or brain
- See how your Tysabri® treatment is working
- Check for any signs of PML – an MRI scan can show early signs even before you or your family/carers spot any changes

The timing of the tests will depend on your Multiple sclerosis (MS) team, and on your probability of developing PML.

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Why are the checks for PML so important?

PML is rare but can be very serious and symptoms may be similar to an MS relapse (e.g. weakness, visual changes or changes in mood or behaviour, and memory lapses). The results from blood tests will help your doctor work out whether you have a higher probability of developing PML. If your doctor or MS nurse is concerned that you may have PML, they will stop your infusions or injections either permanently, or until they can confirm that you do not have PML. An MRI scan will be used to help determine if PML has developed.

If you do develop PML – and remember, it is rare – the earlier your MS team spot it, the better.

If you do have PML, you will no longer be able to have Tysabri®, and you may have to undergo treatment that removes Tysabri® from your blood.

The symptoms of PML can be similar to an MS relapse but develop more slowly and get steadily worse, so it is important to be aware of any new symptoms you develop.[3]

For more information on PML, see the managing side effects section of this booklet.

THINGS TO CONSIDER

Talk to your partner, family or caregiver about PML and its symptoms. They may notice changes in your mood or behaviour, memory lapses, speech and communication difficulties before you do

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How can I track my own health?

You can use a paper or electronic diary or calendar to record how you feel and what changes Tysabri® is making to your Multiple sclerosis (MS) symptoms. You can also use this to keep note of any other issues that you want to discuss with your Multiple sclerosis (MS) team.

SUGGESTIONS

☑ Track how you are feeling, and note down any symptoms and side effects

REMINDER

If you experience anything that is unusual or is bothering you, speak with your Multiple sclerosis (MS) team straight away

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Managing side effects of TYSABRI®

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Managing how I feel on Tysabri®

When you have Multiple sclerosis (MS), monitoring your symptoms and how you respond to treatments is an important way to understand your condition and how to manage it. It allows you to learn what you are capable of, and supports you as you collaborate with your Multiple sclerosis(MS) team in decisions that will affect you and your Multiple sclerosis (MS).

Tysabri® can be delivered as a subcutaneous injection (under the skin), or as an intravenous infusion. Both methods of delivery can cause side effects, and these side effects may differ depending on the delivery method.

Will I experience side effects when receiving Tysabri®?

All medicines may cause side effects. Some side effects are rare, and most people will never experience them, while others are more commonly seen. The same is true for side effects relating to Tysabri®. Some of the side effects of Tysabri® are related to how Tysabri® affects the body's immune system.

It is a good idea for you to understand your treatment and monitor any symptoms so you can discuss these and your progress with your Multiple sclerosis (MS) team.
If you notice anything unusual while you are receiving Tysabri®, whether you think it is a result of the medicine or not, you should get in touch with your Multiple sclerosis (MS) team right away.

Receiving Tysabri® by subcutaneous injection: What are the side effects?

Very common side effects that may affect more than 1 in 10 people receiving Tysabri® by subcutaneous injection include:

- Urinary tract infection
- Sore throat and runny or blocked up nose (nasopharyngitis)
- Headache
- Dizziness
- Joint pain (arthralgia)
- Tiredness (fatigue)
- Feeling sick (nausea)

REMINDER

There is a full list of all the possible side effects in the leaflet that comes with your Tysabri®. Although this list may seem long, you may not experience any of these side effects. But it is important to be aware of what to look out for

REMINDER

Your Multiple sclerosis (MS) team will monitor you during your Tysabri® treatment.

You should let them know immediately if you notice any of these symptoms

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Will I have an allergic reaction to Tysabri®?

A few people receiving Tysabri® may experience signs of allergy during or shortly after it has been administered (either by infusion of injection). If you are going to experience an allergic reaction it is most likely to happen when Tysabri® is first started (after 1 or 2 doses) or if it is restarted after a break of 3 months or more.

Your Multiple sclerosis (MS) team will monitor you during your infusion or injection, and for 1 hour afterwards for any signs of an allergic reaction. If you experience any of the following signs of allergy during or shortly after you receive your dose of Tysabri®, you should let your Multiple sclerosis (MS) team know immediately:

- Swelling of the face, lips or tongue
- Difficulty breathing
- Increase/decrease in blood pressure
- Chest pain or discomfort
- Itchy rash (hives)

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Speak to your doctor or nurse immediately if you experience any of the following, as they may be a sign of a brain infection:

- Seizures (fits)
- Headache
- Nausea
- Changes in personality and behaviour (e.g. confusion, delirium or loss of consciousness)
- Stiff neck
- Extreme sensitivity to bright light
- Fever
- Rash

It is important to fully understand your treatment and monitor any symptoms you experience, so you can discuss these and your progress with your Multiple sclerosis (MS) team. Your Multiple sclerosis (MS) team will support you with this.

If you notice anything unusual while receiving Tysabri®, whether you think it is a result of the medicine or not, you should get in touch with your Multiple sclerosis (MS) team immediately. Please refer to the patient information leaflet for Tysabri® for further information.

Other medicines and Tysabri®

Because of the way Tysabri® affects the immune system, you must not take Tysabri® if you are being treated with other medicines for Multiple sclerosis (MS). You may not be able to use Tysabri® if you are currently taking or have previously received medicines that affect your immune system.

It is important to let your Multiple sclerosis (MS) team know of any other medicines you are being treated with, even if they are unrelated to your Multiple sclerosis (MS). This includes any medicines prescribed by other doctors or those that you buy without a prescription.

REMINDER

A Patient Alert Card contains important safety information that you need to be aware of before, during, and after treatment and will be given to you before treatment. Always carry your card and show it to any healthcare professional involved in your treatment. You should continue to carry your card for 6 months after you stop treatment with Tysabri®.

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Tysabri® and PML

What is PML?

Progressive multifocal leukoencephalopathy, also called PML, is a rare but serious viral infection of the brain that may lead to disability or death.[1] Tysabri® can increase the probability of infections including PML, though cases of PML amongst patients taking Tysabri® are uncommon. It is important for people receiving Tysabri® to be aware of PML, and recognise its symptoms to better manage the impact.

REMINDER

Multiple sclerosis (MS) teams have systems in place to help assess, monitor and manage people who may develop PML. You can also inform your friends and family of the early signs of PML to help support you

What is the probability of developing PML?

There are certain factors that may increase your probability of developing PML. These are:

1) Having antibodies to the **JC virus** in your blood from an earlier JC virus infection
2) The duration of exposure to Tysabri® – the longer you have been treated with Tysabri® – the higher the probability, especially if you have been on treatment for more than 2 years
3) If you have previously used medicines that inhibit or prevent the activity of the immune system (medicines known as immunosuppressants, for example mitoxantrone, cyclophosphamide, azathioprine)

PML is rare and the risk of developing is low in the first 2 years of treatment with Tysabri®.

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What is the JC virus?

The JC virus is a common virus that infects people but does not normally cause noticeable illness. It is completely unrelated to Multiple sclerosis (MS).

Most people have been exposed to the JC virus (most commonly during childhood) without knowing it or experiencing any symptoms. However, the JC virus may increase the probability of developing PML in people who have an altered immune system, such as those receiving Tysabri®.

A simple blood test can be used to determine your **JC virus status**. The results of this test are available after several weeks and will let you and your Multiple sclerosis (MS) team know:

- Whether you have antibodies to the JC virus in your blood **(JC virus positive)** or not **(JC virus negative)**
- The amount of antibodies to the JC virus in your blood (**index value**)

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What is my individual probability of developing PML?

Your own individual probability of developing PML depends on the results of these blood tests. Your Multiple sclerosis (MS) team will discuss your test results with you to help you work out your individual probability of developing PML.

Some people are considered at higher probability of developing PML than others:

- People who are positive for the JC virus have a greater probability of developing PML compared with people who are negative for the JC virus
- The index value shows the amount of antibodies to the JC virus in your blood. The higher the index value, the greater the probability of developing PML than those with a lower value. Those with a higher index value will be monitored more closely

The table on page 40 will help you understand your individual probability of developing PML.

Will my JC virus status change?

Broadly, JC virus status remains relatively stable, however, for a few people their status will change from JC virus negative to JC virus positive. Testing is advised every 6 months to identify people who change from negative to positive.

If you are currently JC virus positive, your index value, and therefore your probability of developing PML, may increase over time. Throughout the course of your treatment, your Multiple sclerosis (MS) team will continue to monitor your individual probability of developing PML.

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What are the symptoms of PML?

The symptoms of PML may be similar to an Multiple sclerosis (MS) relapse (e.g. weakness or visual changes). Therefore, if you believe your Multiple sclerosis (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.

Speak with your partner or caregivers and inform them about your treatment. Symptoms might arise that you might not become aware of by yourself, such as changes in mood or behaviour, memory lapses, speech and communication difficulties, which your doctor may need to investigate further to rule out PML. You should remain aware for symptoms that might arise for up to 6 months after stopping Tysabri® treatment.

The common symptoms of PML are:

- Memory lapses
- Behavioural changes (may first be noticed by friends, family or caregiver)
- Changes in speech and communication
- Progressive weakness affecting one side of the body
- Vision problems

REMINDER

The symptoms of PML may be similar to Multiple sclerosis (MS) symptoms, so keep track of your symptoms and speak to your doctor as soon as possible if you, or your partner or caregivers, notice any changes

If your Multiple sclerosis (MS) team suspects that you have developed PML based on your symptoms and/or any MRI scans, you will be tested. During this time, your Tysabri® treatment will be stopped until it is confirmed that you do not have PML.

REMINDER

It is very important that you contact your Multiple sclerosis (MS) team if you experience **any** new symptoms, even if you think the symptoms are minor or they disappear after a short time. Identifying new symptoms early allows for your Multiple sclerosis (MS) team to better manage your Multiple sclerosis (MS) and improve how you feel

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<Inclusion of efficacy information is dependent on local market regulations and compliance, adapt or remove as necessary. Please note that in many markets, patient facing information on treatment efficacy might be considered promotional>

What happens if I develop PML?

If you develop PML, you will stop being treated with Tysabri®. Your MS team will develop a plan to help manage PML tailored to your individual needs.

What are the benefits and risks of being treated with Tysabri®?

Treating Multiple sclerosis (MS) is a balance between the potential risks (of side effects) and the potential benefits to your Multiple sclerosis (MS) and your health.

Receiving Tysabri® as prescribed decreases the number of relapses and slows the physical challenges that may arise with Multiple sclerosis (MS). Sometimes the effects of Tysabri® are gradual, so that it's only when you think back over a few months or a year that you notice you are feeling better.

In clinical trials, Tysabri® has been shown to reduce the number of Multiple sclerosis (MS) relapses and the worsening of disability in people with Multiple sclerosis (MS) compared with those who received dummy treatment (placebo).

Your treatment with Tysabri® will be reviewed by your Multiple sclerosis (MS) team at regular intervals. During the review, you and your Multiple sclerosis (MS) team will work together to make sure that any decision about your treatment feels right for you. This will be based on your Multiple sclerosis (MS), the benefits to you of treatment with Tysabri® and your personal risk profile.

REMINDER

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

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Your JC virus status and what

The table below provides information on the probability of developing PML based and immunosuppressant use prior to receiving Tysabri®. You can use this in discussi

To read the table, find your JC virus status in the first column. If you are JC virus po have previously used immunosuppressants or not (see Tysabri® and PML section on level, if available, which can be provided by your Multiple sclerosis (MS) team, in the Tysabri®.

For example, if you were in a group of 10,000 people who are JC virus positive, hav and have been taking Tysabri® for 2 and a half years, your probability of developing

			Probabilit	
	JC virus status	**Index level*,6**	**Year 0–1**	**Year 1–2**
JC virus antibodies have been detected in your blood	JC virus positive and you ***have NOT previously used an immunosuppressant medicine***	0.9 or less	1 in 10,000 people	1 in 10,000 people
		More than 0.9 to 1.5	1 in 10,000 people	3 in 10,000 people
		More than 1.5	2 in 10,000 people	9 in 10,000 people
	JC virus positive and you ***have previously used an immunosuppressant medicine***	Index values are not recorded for this group of people	3 in 10,000 people	4 in 10,000 people
You do not have JC virus antibodies in your blood	JC virus negative	There is no index level if you are JC virus negative	←	

*This is the amount of JC virus antibodies in your blood. The higher this value, the greater the probability of If you are JC virus positive, this probability increases over time. †The decrease in PML risk in this group is d

it means

on your JCV status and index levels, the number of years of treatment with Tysabri®
on with your doctor.

sitive, select which of the green sections applies to you, depending on whether you
page 46 for more information about immunosuppressants). Then find your index
e second column and align this with the number of years you have been treated with

e not previously used an immunosuppressant medicine, have an index level of 0.9
PML would be 2 in 10,000 (ie 2 out of these 10,000 people would develop PML)

y of developing PML during treatment with Tysabri®[8]**

Year 2–3	Year 3–4	Year 4–5	Year 5–6
2 in 10,000 people	4 in 10,000 people	5 in 10,000 people	6 in 10,000 people
8 in 10,000 people	20 in 10,000 people	20 in 10,000 people	30 in 10,000 people
30 in 10,000 people	70 in 10,000 people	80 in 10,000 people	100 in 10,000 people
40 in 10,000 people	80 in 10,000 people	80 in 10,000 people	60 in 10,000 people†
1 in 10,000 people →			

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developing PML. **The probability of developing PML is low in the first 2 years of treatment with Tysabri®.
due to a low number of patients treated with Tysabri® for 6 years or longer.

Notes

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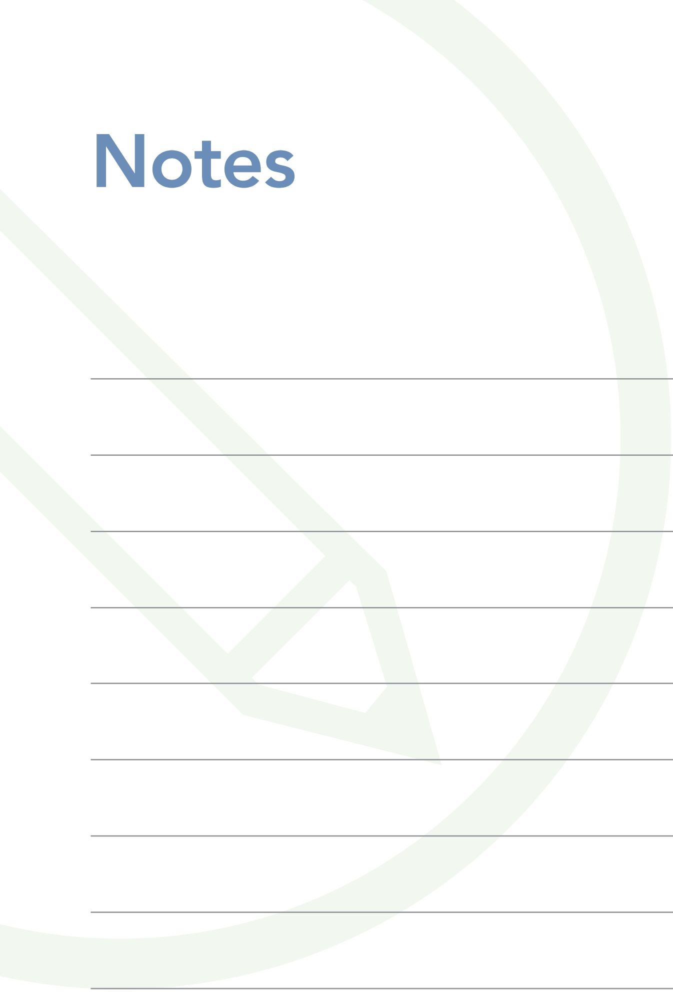

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To report any adverse events, please contact:

Saudi Food and Drug Authority (National Pharmacovigilance Center)
Online: http://ade.sfda.gov.sa
Email: **npc.drug@sfda.gov.sa** Telephone: **19999**

Biogen Technical Scientific office – Branch of Biogen International GmbH – Kingdom of Saudi Arabia: Email: **Safety.Saudi@biogen.com**

PV Hotline: **+966 552885028**

This material is approved by the Saudi food & drug authority.
For extra copies please send an email with the required amount & contact number to: **Safety.Saudi@biogen.com**

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