



Eastern Health MS Service

Tysabri® Therapy

Information for People with MS and their Families

The Eastern Health MS Service has developed this information for you as a guide through what will happen to you on Tysabri® (also called Natalizumab) therapy.

By now, you and your Neurologist have already talked about Tysabri® as an MS treatment option for you. This resource is an addition to your ongoing discussions with your Neurologist and MS Nurse. We want to assure you that the MS team is always available to answer any further questions you may have.

Before Starting Tysabri® Therapy

1. How Tysabri® works, how it will affect you and what to expect from the therapy

What is Tysabri® and how does it work for people with MS?

In MS, inflammation occurs in the brain and damages the nerve cells and the protective covering of the nerve cells (the myelin). Inflammatory cells, called white blood cells, cross over into the brain and produce abnormal patches of inflammation that result in MS lesions. Tysabri® is a protein that binds like a lock and key to these white blood cells, preventing the cells crossing from the blood stream into the brain and causing inflammation and damage.

What are the side effects of Tysabri® and how will it make me feel?

Tysabri® has some unwanted side effects in a small percentage of people. It is very important that you understand and have had an opportunity to discuss possible side effects of Tysabri®.

Common side effects

The most common side effect which occurs in about 25% of people on Tysabri® is an infusion reaction. These reactions usually mild and resolve quickly with or without medications. Such reactions may include headache, nausea, fatigue or dizziness and joint pain. If you experience any of these symptoms, please advise the nurse administering Tysabri®.

Rare side effects

In less than 1% of patients, a more serious hypersensitivity or allergic reaction can occur. Symptoms of this type of reaction may include:

- an itchy rash, hives
- swelling of your face, lips, tongue or other parts of the body
- shortness of breath, wheezing, difficulty breathing or chest pain.

You need to speak to your nurse immediately if you notice any of these symptoms during or after your infusion. These reactions are treatable with medications, but require immediate medical attention and an additional observation period (4 hours).

Very rare side effects

Progressive Multifocal Leukoencephalopathy (PML)

The risk of this illness is very low (1 in 4000) however this is a very serious problem that can result in death or serious disability. The cause of PML is a virus attacking the brain. There are no tests that can screen for PML before you start therapy, however early diagnosis is important in improving long term outcomes. It is very important you inform your MS nurse or doctor of any new symptoms that are persisting beyond two days (for example confusion or impaired thinking, or changes in strength, balance or vision). The use of other immunosuppressive and cancer drugs in combination with Tysabri® may increase the risk of PML. You should never take other immunosuppressive medication, interferon or Copaxone® at the same time as Tysabri®.

Other Opportunistic Infections

Other Opportunistic Infections (such as herpes and chest infections) have been rarely reported with Tysabri®.

Liver Function Test abnormalities

Rare cases of reversible liver damage (less than 1 in 1000) have been reported. A blood test will be performed to check your liver function after the first dose, second dose and fifth dose.

2. Investigations and assessment before you start your first dose

Before you start Tysabri® therapy you will need to have a number of tests to help in the early detection and prevention of any possible side effects. Your neurologist and MS Nurse can help explain these tests and can give you the test results as soon as they are available.

The tests include:

Blood tests

These tests assist in establishing some of your normal bodily patterns. We are then able to detect any changes should they occur and help us monitor your liver function, immune system and overall immune functioning. These tests are called Full Blood Examination (FBE) and Liver Function Test (LFT).

Further blood tests which are required before starting Tysabri® relate to the rare risk of Tysabri® therapy making you more susceptible to a worsening of certain types of viruses and infections if you already have them in your body. These tests include checking for chicken pox virus (Varicella), Hepatitis B and C viruses and Human Immunodeficiency virus (HIV). Currently, no blood test is available to screen for PML.

MRI brain scan

An MRI of your brain is necessary within 3 months of starting Tysabri®. This MRI is used as a comparison to later MRIs to detect any changes during therapy.

Once all of these tests have been completed and the Neurologist has looked at the results and talked them over with you, you are ready to start therapy. The MS team will write a letter to your local doctor and any other health professionals you nominate to let them know that you will be starting the therapy.

3. Considerations before starting Tysabri® Therapy

Tysabri® is a monthly therapy

Tysabri® therapy requires a day admission to hospital every 28 days (4 weeks). If there is interruption to this routine treatment, there is a risk of a serious reaction developing that may mean you have to stop treatment altogether. If exceptional circumstances prevent you from attending your appointment, there is a small window (plus or minus one week in which you can receive the treatment. It is strongly recommended that you take time to consider the impact that this regime will have on your lifestyle **before** you decide to start Tysabri®.

To help you consider its impact you are asked to consider these questions:

- Are you planning a long overseas holiday?
- What impact will this treatment pattern have on your work commitments?
- Does your work require you to travel frequently?
- What other time commitments (such as non-work meetings or events) will interfere with your treatment regime?
- Are you planning to have a family or extend your family?

Taking the time to discuss these issues with your family, friends and health care team will mean that you are prepared and able to make the commitment required for this continuous therapy.

Fertility, pregnancy and contraception

Tysabri® is not recommended during pregnancy or breastfeeding and should be discontinued three months before planning to become pregnant. If you suspect that you are, or may be, pregnant during this therapy **you must** notify your health care team before you have any further doses of Tysabri®.

If you are planning to extend your family you will need to discuss this issue your Neurologist.

Studies in male fertility in animals found no genetic changes in male sperm. In female animals, high doses of Tysabri® caused increased risk of miscarriage.

It is recommended that all men and women receiving Tysabri® should practice medically effective contraception, such as the contraceptive pill or a combination of barrier methods.

Beginning Tysabri® Therapy

1. The Tysabri® Therapy Service at Eastern Health

The Eastern Health MS Service strives to provide you with a Tysabri® service that provides optimal care and fits in with your lifestyle. As part of this goal, the MS Nurse is available at any stage of your Tysabri® therapy journey to listen, answer your questions, and endeavour to meet your needs.

When can I receive my treatment?

The Tysabri® Infusion Service is currently provided on Saturday and occasional Thursday afternoon sessions. The MS Nurse will discuss with you the timing of your session before you start therapy.

Where is the Tysabri® Infusion given?

The Tysabri® infusion is given in a Day Infusion Centre (also called Day Oncology Unit) on the 3rd Floor of the main building of Box Hill Hospital. To get to the Infusion Centre take the lift with the red dot and exit at the third floor.

Getting to and from the Infusion Centre

There is no medical reason why you can't drive yourself to and from the Infusion Centre. However, you may feel more comfortable having a family member or friend drive you, especially for the first infusion. Please ask the MS Nurse about parking arrangements and she will explain the options. All-day parking is available along Nelson road opposite the hospital.

How long does it take to give the Infusion?

The Infusion Centre is set up with comfortable recliner chairs. When you arrive you will be admitted and your paperwork completed and then you can find yourself a comfortable chair. You will be required to complete a short Tysabri® questionnaire. The nurses will then prepare and start the infusion. The infusion itself takes 2 hours. The total time required for an Infusion session is usually about 3 hours.

Who administers the Infusion?

The nursing staff who care for you during the Infusion sessions have received specialist training in the administration of Tysabri®. We aim to ensure that you have the same nurses at your sessions so that you get to know each other and so, over time, the nurses come to understand your individual needs.

The MS Nurse will be available at the time of Infusion to support you and to answer any questions you may have.

A medical Neurology team and Neurologist will be on call to help if needed.

Respecting and caring for others

Other people will be at the Infusion Centre receiving Tysabri® and other specialised infusions during the day. While you may wish to speak to the people around you we do ask that you speak quietly and ensure that you ask the person's permission before you approach them. We must respect people's desire and need for privacy.

Television sets are available. You may like to bring something to read or listen to. You can bring a family member or friend to keep you company. However, for your own and other's comfort and safety, we ask that you bring only one other person and arrange care for children at home. If you are not able to arrange care at home for your children, please speak to the MS Nurse to examine possible alternatives.

If I can't attend can I miss a dose?

Tysabri® is a therapy that needs to be given every 4 weeks. It has been demonstrated that if you miss a dose you have an increased risk of a serious infusion reaction occurs that means you can no longer receive therapy. Only under exceptional circumstances could the possibility of an alternate infusion date be considered, this must be discussed with the MS team well in advance.

Your First Infusion of Tysabri®

The first step is often the most challenging as many people who start Tysabri® feel apprehensive about the first dose. The MS Nurse will be available to provide you with reassurance and answer any questions you have.

The Tysabri® Infusion Journey

Complete the pre-infusion questionnaire and go through it with the nurse, discussing any changes in your health and well-being, any new medications or any concerns.

Your blood pressure, heart rate and temperature will be checked and any other necessary assessments done.

Tysabri is given directly into vein into your arm. A nurse will insert an intravenous cannula (commonly called a 'drip') will be inserted into your arm.

Tysabri 300mg is then added to a bag of fluid called 100ml Normal Saline. A tube is connected to the cannula in your arm and the fluid is given over 1 hour.

When the bag is empty, another bag of 100mls Normal Saline is given over 1 hour. This hour is the **observation period**.
It is a medical requirement that you are to be observed and monitored for 1 hour

During the infusion and observation period your blood pressure, heart rate and temperature will be checked regularly.

Following the **Infusion** and observation period (2 hours) your cannula will be removed, the nurse will discuss follow-up and appointments with you, you will be given the date for your next Tysabri® Infusion and then you are able to be discharged home.

Ongoing Tysabri® Infusions

The next Tysabri® Infusion will be given to you in a similar way. The Nurse may spend more time with you discussing your experience of the previous Infusion and any problems you may have experienced. Prior to each infusion it is important that you tell the nurse if you have:

- experienced any changes in your MS
- had any health problems, including any infections, colds or viruses
- commenced, stopped or changed any medications
- experienced any significant lifestyle challenges or changes
- **become pregnant or are considering having children** (relevant to male and female patients)
- any other concerns or problems.

1. Monitoring and follow-up

You will need to visit your Neurologist at the following times:

- between the first and third dose
- between the fifth and sixth dose
- every six months thereafter.

You will also require a blood test to test your liver function after your first, second and sixth dose of Tysabri®.

The MS Nurse will be available at every Infusion session to answer your questions or concerns and is available via:

EMAIL: jodi.haartsen@easternhealth.org.au or on

OFFICE: MS office 9895 4914 on Tuesday, Thursday and Friday

MOBILE: 0412 361 377 at any other time for help when you need it.

2. Planning for pregnancy

Tysabri® is not recommended in pregnancy or while breastfeeding. If you (male or female) are planning for pregnancy, please consider your timelines carefully before starting Tysabri®. If you would like to become pregnant (male or female) and are currently receiving Tysabri®, please discuss this with your MS Nurse or MS Neurologist as you must discontinue Tysabri® therapy before trying to conceive a child.