

Patient Guide

Important Information for Patients
Starting Therapy with **LEMTRADA**



LEMTRADA[®]
alemtuzumab^{12mg} _{iv}

What is LEMTRADA and how does it work?

LEMTRADA is a prescription medicine used to treat relapsing remitting multiple sclerosis (MS) in adults. LEMTRADA does not cure MS but it can decrease the number of MS relapses. It can also help to slow down some of the signs and symptoms of MS.

Multiple sclerosis (MS) is an autoimmune disease that effects the central nervous system (brain and spinal cord). A substance called myelin protects the nerve fibres in the central nervous system, which helps messages travel quickly and smoothly between the brain and the rest of the body. Normally, your immune system protects your body from attack by organisms which cause disease. In MS, cells responsible for attacking invading organisms (“lymphocytes”, a type of white blood cell) can mistakenly the myelin that forms a protective layer around nerve fibres.

When your lymphocytes attack your nervous system, this causes inflammation which is often associated with a relapse. The symptoms you experience are determined by which part of your central nervous system is affected. The damage done during this inflammation may be reversible, but as your disease progresses the damage may accumulate and become permanent.

LEMTRADA adjusts your immune system to limit its attacks on your nervous system. After having a course of treatment with LEMTRADA you may be at greater risk of developing other autoimmune conditions, or experiencing serious infections. It is important you understand these risks and how to monitor for them.

How is LEMTRADA given?

LEMTRADA is put into your veins through a needle (an infusion). LEMTRADA is given in two courses of treatment. The first course will be given for 5 days in a row. Then, one year later, the next course will be given for 3 days in a row. LEMTRADA is not like some other drugs that you have to take regularly (for example, once a day) to have an effect. Clinical trials have shown that the 2 courses work for most patients for 2 years or sometimes longer. You will need to be monitored for side effects for 4 years after your last infusion of LEMTRADA. This is described below.

Will I need to have any tests done after treatment with LEMTRADA?

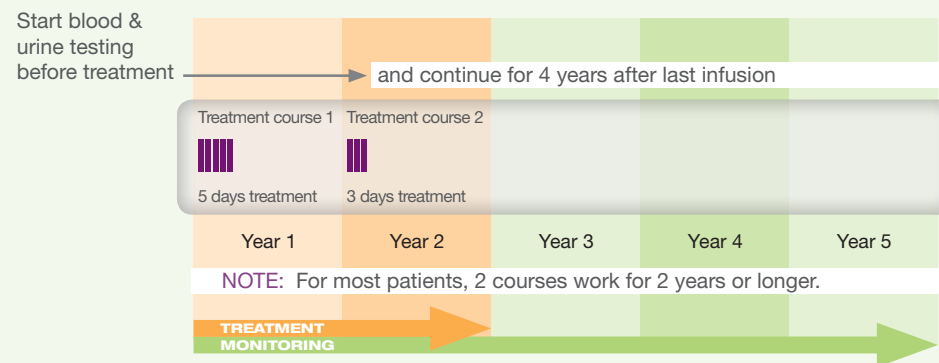
To check for the development of autoimmune conditions, you will have to be monitored monthly by having your blood and urine tested. Your doctor will check the results of these tests to see if you have developed a side effect.

It is very important that you continue to have these checks for 4 years after your last course of treatment with LEMTRADA, even if you are feeling well (no symptoms or side effects) and your MS symptoms are under control. Side effects may occur many years after your last course of treatment with LEMTRADA, and they may be (in rare cases) life-threatening, so it is very important you continue to be checked, and that you watch out for symptoms. This will allow a problem to be detected and treatment to begin right away.

This means you commit to the monthly lab tests, continuing for 4 years after your last course of treatment with LEMTRADA. You and your doctor will work together as a team to make sure you get these tests done, and to plan them around your normal activities. If you are a woman, it is also important to avoid urine testing during your menstrual period as this may give a false result.

The duration of the effects of treatment and the length of required follow-up, please refer to the diagrams below titled Overview of LEMTRADA Treatment and Overview of LEMTRADA Monitoring.

Overview of LEMTRADA Treatment



Overview of LEMTRADA Monitoring

The following table shows you which tests are done, when, and for how long.

Test	When	For how long?
Blood test	Before treatment starts and every month after treatment	Until 4 years after your last LEMTRADA infusion
Urine test	Before treatment and every month after treatment	Until 4 years after your last LEMTRADA infusion

Delayed side effects

Immune Thrombocytopenic Purpura (ITP) (a bleeding disorder)

ITP is a condition which results in a decrease in the number of platelets in the blood. Platelets are necessary for normal blood clotting. ITP can cause severe bleeding. If detected promptly it is treatable, but if left untreated it may lead to serious health problems and possibly death.

A blood test will help your doctor watch for changes in your platelet count, in order to catch this side effect early. Therefore, your doctor will have your blood tested before starting LEMTRADA, and on a monthly basis after your initial treatment course. The monthly testing must continue for 4 years after your last treatment course.

Importantly, ITP can also be detected by certain signs and symptoms that you need to be aware of.

What are the signs and symptoms of ITP?

- Small scattered spots on your skin that are red, pink or purple
- Easy bruising
- Bleeding from a cut that is harder to stop
- Heavier, longer or more frequent menstrual periods than normal. Bleeding between your menstrual periods could also be a sign of ITP
- Bleeding from your gums or nose that is new or takes longer than usual to stop
- Coughing up blood

Call your doctor immediately if you have any of these signs or symptoms. If you cannot reach your doctor seek immediate medical attention.

What if I develop ITP?

It is best to identify and treat ITP **as early as possible**. That is why it is so important that you continue to have your monthly blood test (which could detect a problem before you have symptoms). It is also important that you, your family members and/or caregivers are watching for any of the signs or symptoms described in this guide. Delaying treatment of ITP raises the chance of more serious problems.

These pictures show some examples of bruises and rashes caused by ITP:

Note: These pictures are only a guide in order to show examples of bruises or rashes



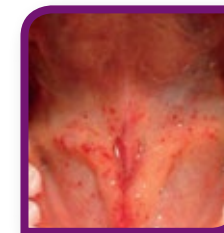
This is an example of a leg with scattered spots under the skin that are red, pink or purple. They might look like pin pricks.

It's important to note that the spots could occur anywhere on your body, not just on your leg



This is an example of arms with easy or excessive bruising.

It's important to note bruises could occur anywhere on your body, not just on your arms



This is an example of spots due to bleeding under the tongue.

This could occur anywhere in your mouth - under the tongue, on the roof of your mouth, on your inner cheeks, on your tongue or on your gums.

If detected early, ITP is usually treatable. If you develop ITP, you and your doctor will decide which treatment is best for you.

If you notice any of the signs or symptoms (as described above), call your doctor right away to report the symptoms. If you cannot reach your doctor seek immediate medical attention.

Kidney Disorders (such as anti-Glomerular Basement Membrane disease)

LEMTRADA may cause a condition known as, anti-Glomerular Basement Membrane or anti-GBM disease. Anti-GBM disease is an autoimmune condition that can result in severe damage to the kidneys. Damage to the lungs may also occur with anti-GBM disease, although this was not seen in clinical trials with LEMTRADA. If untreated it can cause kidney failure requiring chronic dialysis or transplantation, and may lead to death.

A blood test and urine test will help your doctor watch for signs of kidney disease to catch this side effect early. Your doctor will have your blood and urine tested before starting LEMTRADA, and on a monthly basis after your initial treatment course. Your doctor will test your urine monthly also. If you are a woman, it is also important to avoid urine testing during your menstrual period as this may give a false result. This testing will continue for 4 years after your last infusion.

Importantly, anti-GBM disease can also be detected by certain signs and symptoms that you need to be aware of.

What are the signs and symptoms of kidney problems or anti-GBM disease?

- **Blood in the urine:** Your urine may be red or tea-colored.
- **Swelling:** Swelling in your legs or feet.
- **Coughing up blood:** You may cough up blood.

What if I develop kidney problems?

Most of the time doctors can treat kidney problems. It is best to begin treatment as early as possible. It is important that you are familiar with the signs and symptoms of kidney problems and anti-GBM disease, and complete your regular laboratory tests (blood tests and urine tests).

Kidney problems will almost always need treatment. Treatment can begin right away, if needed.

If you notice any of the signs or symptoms as described, call your doctor right away to report the symptoms. If you cannot reach your doctor seek immediate medical attention.

Thyroid Disorders

The thyroid is a gland found in the lower part of the neck. This gland produces hormones that are important throughout your body. In some people, the immune system may mistakenly attack the cells of the thyroid gland (autoimmune thyroid condition) which affect its ability to make and control the level of hormones.

LEMTRADA may cause development of thyroid disorders including:

- **Over-active thyroid gland – or Hyperthyroidism:** This condition is when the thyroid produces too much hormone.
- **Under-active thyroid gland – or Hypothyroidism:** This condition is when the thyroid does not produce enough hormone

Your blood will be checked before starting your treatment with LEMTRADA, and every 3 months after your initial treatment course until 4 years after your last infusion. This blood test will help your doctor detect thyroid disorders early.

What are the signs and symptoms of an over-active thyroid?

Symptoms may include:

- Excessive sweating
- Unexplained weight loss
- Eye swelling
- Nervousness
- Fast heartbeat

What are the signs and symptoms of an under-active thyroid?

Symptoms may include:

- Unexplained weight gain
- Feeling cold
- Worsening tiredness
- Newly occurring constipation

What if I develop a thyroid disorder?

Tell your doctor if you experience these symptoms.

Depending on the type of thyroid disorder you are experiencing, your doctor will decide which treatment is best for you. It will be important to follow your doctor's recommendations to be sure to benefit the most from your treatment. In some cases, you will have to take medication for the rest of your life for your thyroid disorder. In some situations, your thyroid may need to be removed.

Should you develop a thyroid disorder, it is very important that you are properly treated for it, especially if you become pregnant after using LEMTRADA. Having an untreated thyroid disorder could harm your unborn baby, or harm your baby after birth.

IMPORTANT!

Since all of these autoimmune conditions could occur long after you received a course of treatment with LEMTRADA, it is very important that you continue to have your monthly tests (even if you are feeling well).

You must also continue to watch for signs and symptoms.

- Do this for 4 years after your last course of treatment with LEMTRADA
- Early detection and diagnosis may give you the best opportunity for improvement.
- Carry your patient alert card with you and show it to any health care providers who are providing you treatment (including for non-MS conditions) or in the event of a medical emergency

Serious Infections

Patients treated with LEMTRADA are at a higher risk for getting a serious infection. If you develop a serious infection you may have to go to hospital for treatment. It's important to tell the doctors in the hospital that you have received LEMTRADA.

If you are suffering from an infection before the initiation of your LEMTRADA treatment, your doctor will consider delaying the treatment until the infection is under control or resolved.

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