Lemtrada®

Alemtuzumab

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Lemtrada.

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

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Lemtrada against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet.
You may need to read it again.

What Lemtrada is used for

Lemtrada contains the active substance alemtuzumab and is used to treat relapsing forms of multiple sclerosis (MS) in adults with active disease who are not stable on current therapy.

Lemtrada slows down the progression of physical disability in people with relapsing forms of MS and decreases the number of flare-ups (relapses).

In MS your immune system mistakenly attacks the protective layer (myelin) around the nerve fibres of your brain and spinal cord, causing inflammation.

Lemtrada works on your immune system so that it may reduce the impact of the disease on your nervous system.

Your doctor, however, may have prescribed Lemtrada 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.

Lemtrada is not intended to be used in children and adolescents as it has not been studied in MS patients below 18 years old.

Before you take Lemtrada

Before treatment your doctor should have discussed the risks and benefits of Lemtrada and the need for you to commit to 48-months of follow-up after the last infusion of Lemtrada

When you must not take Lemtrada

Do not take Lemtrada if you:

- have an allergy to alemtuzumab (the active ingredient) or proteins of mouse origin, or any of the ingredients listed at the end of this leaflet.

Symptoms that may indicate an allergic reaction 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

These symptoms may also occur as a non-allergic reaction to Lemtrada infusion. Tell your doctor if you are experiencing these symptoms.

Lemtrada should not be used after the expiry date (exp) printed on the pack.

Lemtrada should not be used if the packaging is torn or shows signs of tampering.

Before you start to take it

Tell your doctor, nurse or pharmacist if you have:

- allergies to any of the ingredients listed at the end of this leaflet
- received a vaccination in the last 6 weeks
- if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby
- bleeding, thyroid or kidney problems
- a recent history of infection
- a malignancy (cancer)
- had a positive HIV, Hepatitis B or C blood test
- uncontrolled hypertension
- have ever had a stroke
- have ever had angina or a heart attack
- a condition where your blood's ability to form clots is impaired, or are taking any medicine to help your blood clot normally
- received an organ transplant
- taken or are taking other medicines to reduce the function of your immune system
- other illness in addition to your Multiple Sclerosis.

Important Information

Talk to your doctor before Lemtrada is given. After having a course of treatment you may be at risk of developing autoimmune conditions (see below) or experiencing serious infections. It is important you understand these risks and how to monitor for them. You will be given a Patient Wallet Card and Patient Guide with further information. It is important you keep the Patient Wallet Card with you during treatment and for 4 years after your last infusion, because side effects may occur many years after treatment. If you have medical treatment,even if not for your MS, show the Patient Wallet Card to your doctor.

Autoimmune conditions

Treatment with Lemtrada may increase the risk for autoimmune conditions. These are conditions where your immune system mistakenly attacks certain cells of your body. Information about some specific conditions is provided below.

These autoimmune conditions can occur many years after treatment with Lemtrada.

You will need to have a blood test and a urine test before starting treatment and every month until 4 years after your last Lemtrada infusion even if you are feeling well and your MS symptoms are under control.

In addition there are certain signs and symptoms that you should look out for yourself. Details are described under Side Effects. More helpful information about these conditions and testing for them can be found in the Lemtrada Patient Guide.

Immune Thrombocytopenic Purpura

Approximately 2% of patients may develop an autoimmune bleeding disorder called Immune Thrombocytopenic Purpura (ITP). This must be diagnosed and treated promptly, as otherwise the effects can be serious or even fatal. ITP can cause bleeding (that may be hard to stop) and/or easy bruising, and/or small scattered spots on your skin that are red, pink or purple.

Your blood will be checked before starting your treatment with Lemtrada, and every month after your initial treatment course until 4 years after your last infusion. This should allow a problem to be detected early and treatment to begin right away. Your doctor will explain symptoms for you to look out for so that you can seek urgent medical help if you experience them.

Thrombotic Thrombocytopenic Purpura

Some patients may develop a bleeding disorder called Thrombotic Thrombocytopenic Purpura (TTP). This must be diagnosed and treated promptly, as otherwise the effects can be serious or even fatal. TTP can cause blood clots form in small blood vessels throughout the body. The clots can limit or block the flow of oxygen-rich blood to the body's organs, such as the brain, kidneys, and heart.

Kidney Disease (such as anti-GBM disease)

Approximately 1 in 250 patients have experienced autoimmune related problems with their kidneys, such as anti-glomerular basement membrane disease (anti-GBM disease). If untreated it can cause kidney failure requiring dialysis or transplantation and may lead to death. Your blood and urine will be checked before starting your treatment with Lemtrada, and every month after your initial treatment course until 4 years after your last infusion. This should allow a problem to be detected early and treatment to begin right away.

Thyroid Disorders

More than a third of patients have experienced an autoimmune disorder of the thyroid gland affecting its ability to make or control hormones that are important for your metabolism. This can result in many different symptoms such as excessive sweating, unexplained weight loss, eye swelling, nervousness, or fast heartbeat. Let your doctor know if you experience any such symptoms. If you develop a thyroid disorder, in most cases you will need to be treated for the rest of your life with medication to control your thyroid disorder, or in some cases your thyroid may have to be removed. 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.

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.

Liver Inflammation

Some patients have developed liver inflammation after receiving Lemtrada. If you develop one or more of the following symptoms report this to your doctor: nausea,

vomiting, abdominal pain, fatigue, loss of appetite, yellow skin or eyes, dark urine, or bleeding or bruising more easily than normal.

Other Autoimmune Conditions

Uncommonly patients have experienced autoimmune conditions with the red blood cells or white blood cells. This can be diagnosed from the blood tests that you will be having after Lemtrada treatment. If you develop one of these conditions your doctor will take appropriate measures to treat it.

Summary of Recommended Testing for Autoimmune Conditions

Blood test - Before treatment starts and every month until 4 years after your last Lemtrada infusion

Urine test - Before treatment starts and every month until 4 years after your last Lemtrada infusion

Liver function test - before treatment starts and every month until 4 years after your last Lemtrada infusion.

Infusion reactions

Most patients treated with Lemtrada will experience side-effects at the time of the infusion or within 24 hours after the infusion. All of these reactions are described in the Side Effects section of this leaflet.

Most infusion reactions are mild but some serious reactions are possible such as change in heart rate, headache, low blood pressure, nausea, chest discomfort, fever or hives. Allergic reactions are possible.

In order to try to reduce these effects, your doctor will give you medication (corticosteroids) prior to the first 3 infusions of a treatment course. Other treatments to limit these reactions can also be given before the infusion or when you experience symptoms. In addition, you will be observed during the infusion and after the infusion has been completed. In case of serious reactions, it is possible that the infusion may be slowed down or even stopped.

Other Serious Reactions Occurring Shortly After Lemtrada Infusion

Some patients have had serious or life-threatening reactions after Lemtrada infusion, including bleeding in the lung, heart attack, stroke or tears in blood vessels supplying the brain. Reactions may occur following any of the doses during the treatment course.

In the majority of cases reactions occurred within 1-3 days of the infusion. Your doctor will monitor vital signs, including blood pressure, before and during the infusion.

Get help right away if you have any of the following symptoms: trouble breathing, chest pain, facial drooping, sudden severe headache, weakness on one side of the body, difficulty with speech or neck pain.

Haemophagocytic Lymphohistiocytosis

Treatment with Lemtrada may increase the risk of excessive activation of white blood cells associated with inflammation (haemophagocytic lymphohistiocytosis), which can be fatal if not diagnosed and treated early.

If you experience multiple symptoms such as fever, swollen glands, bruising, or skin rash, contact your doctor immediately

Infections

Patients treated with Lemtrada may be at a higher risk for getting a serious infection. 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.

Most infections seen in clinical trials were mild to moderate and most often included airway infections such as colds, bronchitis and sinus infections, cystitis, cold sores, or influenza (flu). However serious infections like appendicitis, gastric flu, pneumonia, chicken pox or shingles and tooth infection have also occurred.

If you have had a herpes infection (e.g. a cold sore) in the past it is possible that this will flare up after treatment with Lemtrada, or you could develop a herpes infection for the first time. It is recommended that your doctor prescribes treatment with a medicine against infections like this, which should be taken during the days that you receive infusions, and for one month following the infusion, in order to reduce the chance of developing a herpes infection.

In addition, infections which can result in abnormalities of the cervix (the neck of the womb) are possible. Therefore it is recommended that all female patients have annual screening performed, such as a pap smear. Your doctor will explain to you what testing will be done to you.

Patients who receive Lemtrada have an increased chance of getting an infection caused by the bacteria, Listeria. Avoid foods that may be a source for Listeria (for example, deli or processed meats, unpasteurized milk and cheese products, or undercooked meat, seafood or poultry) or make sure that the food you eat which may contain Listeria is heated well if you receive treatment with Lemtrada.

You may be tested for tuberculosis according to your doctor's decision.

Fungal (yeast) infections of the mouth (oral thrush), and vagina (vaginal thrush) have also been seen.

If you are a carrier of hepatitis B or hepatitis C infection (these affect the liver), extra caution is needed before you receive Lemtrada treatment as it is unknown if treatment could lead to activation of the hepatitis infection which could subsequently damage your liver.

Inflammation of the Gallbladder

Lemtrada may increase your chance of getting inflammation of the gallbladder. This may be a serious medical condition that can be life threatening. You should report to your doctor if you have symptoms such as stomach pain or discomfort, fever, nausea or vomiting.

Previously Diagnosed Cancer

If you have been diagnosed with cancer in the past, please inform your doctor about it.

Vaccines

It is unknown if Lemtrada has an impact on your ability to raise a response to a vaccine. If you have not completed the standard required vaccinations, your doctor will consider whether you should have them before your Lemtrada treatment. In particular, your doctor will consider vaccinating you against chicken-pox if you have never had it. Any vaccination will need to be completed at least 6 weeks prior to starting a Lemtrada treatment course.

After your treatment course with Lemtrada, consult your healthcare provider if you require vaccination. Your healthcare provider will determine if it is safe for you to do so. You must not receive certain types of vaccines (live viral vaccines) if you have recently received Lemtrada.

Pregnancy and Breast-feeding

Woman of childbearing potential should use effective contraceptive methods during treatment with Lemtrada and for 4 months after each course of treatment.

If you become pregnant after treatment with Lemtrada and experience thyroid problems during pregnancy, extra caution is needed. The thyroid problems could be harmful to the baby.

It is unknown if Lemtrada can be transferred to a baby through breast milk, but there could be a risk. You should not breast-feed during each course of treatment with Lemtrada and for 4 months after each treatment course.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines (including vaccinations).

Besides Lemtrada, there are other treatments (including those for MS, or to treat other conditions) which could affect your immune system and so could affect your ability to fight infections. If you have used another MS treatment in the past, your doctor may ask you to stop the other medicine in advance of starting treatment with Lemtrada.

How Lemtrada is given

How it is given

Lemtrada will be given to you as an infusion into a vein. Each infusion will take approximately 4 hours.

How often is it given

The initial treatment you will receive will consist of one infusion (12mg) per day on 5 days (course 1) and one infusion (12mg) per day for 3 days one year later (course 2). There is no Lemtrada treatment between the two courses.

Some patients, if they have symptoms or signs of MS disease activity after the initial two courses may receive one or two additional treatment courses. In case you need an additional treatment course you will receive one infusion per day for three days administered at least a year after the prior treatment.

Once you have received Lemtrada, you will need to undergo regular tests to ensure that any potential side-effects can be diagnosed and treated promptly. Monitoring must continue for 4 years after the last infusion.

If you receive too much (overdose)

As Lemtrada is given to you under the supervision of a doctor or nurse, it is very unlikely that you will receive too much. However, if you experience any unexpected or worrying side effects after being given Lemtrada tell your doctor, pharmacist or nurse as soon as possible.

While you are taking Lemtrada

Things you must do

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from

your pharmacy, supermarket or health food shop.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Lemtrada.

Woman of childbearing potential should use effective contraceptive methods during treatment with Lemtrada and for 4 months after each course of treatment.

Things to be careful of

Lemtrada does not directly affect your ability to drive or use machines. However you may experience a side-effect during the treatment course which could make this unsafe, for example dizziness. If affected, stop these activities until the side-effect resolves.

Side Effects

Tell your doctor, pharmacist or nurse as soon as possible if you do not feel well while you are taking Lemtrada.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

There have been reports of a rare, serious brain infection called PML (progressive multifocal leukoencephalopathy) in patients receiving some medicines for MS. PML can cause severe disability or even death. Symptoms of PML can be similar to those of MS.

Tell your partner or carer about your Lemtrada treatment, especially if you have received other medicines to treat MS before. They might notice symptoms that you do not, such as changes in movement or behaviour, that your doctor may need to investigate further.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- trouble breathing
- chest pain
- pressure, tightness, pain, or a squeezing or aching sensation in your chest or arms that may spread to your neck, jaw or back.
- lightheadedness or sudden dizziness
- drooping of the skin on your face
- sudden weakness or numbness on one side of the body
- sudden difficulty with speech or blurred vision
- neck pain
- sudden severe headache
- pain in your scalp, face or neck
- eye pain
- pulsing sound in the ear

If any of the following happen after you have been given Lemtrada tell your doctor or nurse immediately. If you cannot reach your doctor or nurse you must seek immediate medical attention:

- small scattered spots on your skin that are red, pink or purple
- any bleeding that is heavier than usual or harder to stop than expected, easy bruising
- blood in the urine, coughing up blood and swelling in your legs or feet
- purplish bruises on the skin or mucous membranes (such as the mouth)
- paleness or jaundice (a yellowish colour of the skin or whites of the eyes)
- fatigue (feeling very tired and weak)
- fever
- a fast heart rate or shortness of breath
- stomach pain or discomfort, fever, nausea or vomiting

If any of the following happen after you have been given Lemtrada tell your doctor or nurse soon so that they are treated promptly:

- signs of infection such as fever and/or chills, swollen glands, mouth or skin ulcers, abscesses, or wounds that take along time to heal
- excessive sweating, unexplained weight loss, eye swelling, nervousness, fast heartbeat
- unexplained weight gain, feeling cold, worsening tiredness, new constipation
- unexplained or excessive tiredness, sore throat, swollen glands in the neck or armpits

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

- side effects that can happen during, or within 24 hours, of the infusion including: headache, rash, fever, feeling sick, hives, itching, reddening of the face and neck, feeling tired
- change in heart rate, indigestion, chills, chest pain, dizziness, strange taste, difficulty sleeping, difficulty breathing or shortness of breath, rash
- muscular or joint pain, sore mouth or gums, feeling weak, vomiting, diarrhoea, stomach pain, gastric flu, heartburn, trembling, burning or prickling sensation
- swelling of arms or legs, prolonged or irregular menstruation, red skin, excessive sweating, nose bleeds and bruising

Refer to your Lemtrada patient guide for further information.

After using Lemtrada

Storage

Lemtrada is stored in the pharmacy or clinic at 2 to 8°C.

Disposal

The Doctor, Nurse or Pharmacist will dispose of any unused Lemtrada.

Product description

What Lemtrada looks like

Lemtrada is a clear colourless to yellowish solution.

Ingredients

Active ingredients:

Each vial of Lemtrada contains 10mg/mL of alemtuzumab

Inactive ingredients:

- sodium chloride
- dibasic sodium phosphate heptahydrate
- potassium chloride
- monobasic potassium phosphate
- polysorbate 80
- disodium edetate
- water for injections

Name and Address of Australian Sponsor

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