Lemtrada®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Lemtrada?

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

For more information, see Section 1. Why am I using Lemtrada? in the full CMI.

2. What should I know before I use Lemtrada?

Do not use if you have ever had an allergic reaction to Lemtrada or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Lemtrada? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Lemtrada and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Lemtrada?

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

More instructions can be found in Section 4. How do I use Lemtrada? in the full CMI.

5. What should I know while using Lemtrada?

Things you should do	• 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 you should not do	• 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.
Driving or using machines	• 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.
Looking after your medicine	• Lemtrada is stored in the pharmacy or clinic at 2°C to 8°C. • The Doctor, Nurse or Pharmacist will dispose of any unused Lemtrada.

For more information, see Section 5. What should I know while using Lemtrada? in the full CMI.

6. Are there any side effects?

Tell your doctor, pharmacist or nurse as soon as possible if you do not feel well while you are taking Lemtrada. There have been reports of a rare but serious brain infection called PML (progressive multifocal leucoencephalopathy) 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.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Lemtrada® (lem-tra-da)

Active ingredient: *alemtuzumab*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Lemtrada. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about Lemtrada.**

Where to find information in this leaflet:

1. Why am I using Lemtrada?

Lemtrada contains the active ingredient alemtuzumab.

Lemtrada 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 fibers 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.

2. What should I know before I use 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.

Warnings

Do not use Lemtrada if:

- you are allergic to alemtuzumab (the active ingredient) or proteins of mouse origin, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

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.

Check with your doctor if you have:

- allergies to any of the ingredients listed at the end of this leaflet
- received a vaccination in the last 6 weeks
- 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
- ever had a stroke
- 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
- taken any medicines for any other condition
- other illness in addition to your Multiple Sclerosis.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Use in Children

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

Pregnancy and Breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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.

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 yeses, dark urine, or bleeding or bruising more easily than normal.

Organ Inflammation

Lemtrada treatment may potentially be associated with an immune disorder (sarcoidosis) that can cause inflammation of one or more organs including lungs, lymph nodes, skin or heart. If you develop one or more of the following symptoms, report this to your doctor: fatigue, swollen lymph nodes, weight loss, pain and swelling in joints, persistent dry cough, shortness of breath, chest pain, changes in heartbeat, blurred vision, eye pain, sensitivity of light, rash or sores on or under your skin.

Autoimmune Encephalitis

This condition may include symptoms such as behaviour and psychiatric changes, movement disorders, short term memory loss or seizures as well as other symptoms resembling an MS relapse.

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.

Adult Onset Still's disease (AOSD)

AOSD is a rare condition that has the potential to cause multi-organ inflammation, with several symptoms such as fever >39°C or 102.2°F lasting more than 1 week, pain, stiffness with or without swelling in multiple joints and/ or a skin rash. If you experience a combination of these symptoms contact your healthcare provider 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.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any vaccinations, medicines, vitamins, or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Lemtrada.

4. How do I use Lemtrada?

How much to take

- Follow the instructions provided and use Lemtrada until your doctor tells you to stop.

When to take Lemtrada

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

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.

You should immediately:

- **by calling 13 11 26** in Australia, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Lemtrada?

Things you should do

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.

Remind any doctor, dentist or pharmacist you visit that you are using Lemtrada.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Lemtrada affects you.

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.

Looking after your medicine

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

When to discard your medicine

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

6. Are there any 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. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about 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.

Less serious side effects

Less serious side effects	What to do
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 **General:** • chills • chest pain • dizziness • strange taste • difficulty sleeping • difficulty breathing or shortness of breath • muscular or joint pain	**Speak to your doctor if you have any of these less serious side effects and they worry you.** **Refer to your Lemtrada patient guide for further information.**

Less serious side effects	What to do
• sore mouth or gums • feeling weak • trembling • burning or prickling sensation • swelling of arms or legs • excessive sweating • nose bleeds • bruising **Skin-related:** • red skin • rash • vitiligo (patches of skin that have lost colour) **Heart-related:** • change in heart rate **Gynecological:** • prolonged or irregular menstruation **Gut-related:** • indigestion, • vomiting • diarrhoea • stomach pain • gastric flu • heartburn	

Serious side effects

Serious side effects	What to do
General: • unexplained weight gain • feeling cold • worsening tiredness, unexplained or excessive tiredness • neck pain • excessive sweating • unexplained weight loss • sore throat • sudden severe headache nervousness • fast heartbeat • 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 • pulsing sound in the ear • pain in your scalp, face or neck **Gut-related:** • stomach pain or discomfort • nausea or vomiting • new constipation **Eye-related:** • eye swelling • eye pain	**Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
Neurological disorder: • sudden weakness or numbness on one side of the body • drooping of the skin on your face • sudden difficulty with speech or blurred vision **Infection:** • signs of infection such as fever and/or chills, swollen glands, mouth or skin ulcers, abscesses, or wounds that take a long time to heal • swollen glands in the neck or armpits • fever	
Skin related: • small scattered spots on your skin that are red, pink or purple • paleness or jaundice (a yellowish colour of the skin or whites of the eyes) • purplish bruises on the skin or mucous membranes (such as the mouth) **Bleeding** • 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	**Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Lemtrada contains

Active ingredient (main ingredient)	Each vial of Lemtrada contains 10mg/mL of alemtuzumab
Other ingredients (inactive ingredients)	• sodium chloride • dibasic sodium phosphate heptahydrate • potassium chloride • monobasic potassium phosphate

	• polysorbate 80 • disodium edetate • water for injections
Potential allergens	**-**

Do not take this medicine if you are allergic to any of these ingredients.

What Lemtrada looks like?

Lemtrada is a clear colourless to yellowish solution.

AUST R 200941

Who distributes Lemtrada?

Australian Sponsor:

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Australia

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