

LEMTRADA[®]
alemtuzumab_{12mg}

Patient Guide

Important safety information you should know when starting therapy with LEMTRADA (alemtuzumab)

The aim of this guide is to help you understand some of the risks associated with alemtuzumab treatment and the monitoring needed to help minimise these risks.

This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Health Care Professionals (HCPs) are advised to report any suspected adverse reactions.

In case of any drug related adverse events, please contact: The National Pharmacovigilance Centre (NPCSaudi Food and Drug Authority (SFDA))
Call Center: 19999

E-mail: npc.drug@sfd.gov.sa
Website: <https://ade.sfd.gov.sa>



For SANOFI Pharmacovigilance center, please contact:+966-544-284-797
E-mail: Ksa_pharmacovigilance@sanofi.com

Risk minimisation information for patients.

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

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Executive summary

A guide to your LEMTRADA (alemtuzumab) infusions for treating relapsing remitting multiple sclerosis (MS).

This is an abbreviated guide – please refer to the full guide for more information. This guide is not intended to replace the Package Leaflet or discussions you have with your doctor or other healthcare professionals who are treating you with LEMTRADA.



LEMTRADA is a treatment for adults with relapsing-remitting multiple sclerosis, used when the disease is very active, worsening despite other treatments, or progressing rapidly, helping to slow its course and reduce relapses.

LEMTRADA can cause serious side effects soon after treatment or even years later, so it's important to watch for symptoms and report them to your doctor, and to keep family or caregivers informed.

Serious infections

Side effect	Signs and symptoms to watch for
Serious infections	Fever, chills, fatigue, shortness of breath, cough, wheezing, chest pain or tightness, coughing up blood
Brain infection (Progressive Multifocal Leukoencephalopathy [PML])	Progressive weakness or clumsiness, vision problems, speech difficulties, or changes in thinking and memory that may cause confusion or personality changes.

Serious side effects occurring shortly after LEMTRADA infusion

Side effect	Signs and symptoms to watch for
Heart attack	Shortness of breath, chest pain or discomfort, coughing blood
Bleeding in the lung	Chest pain or discomfort, shortness of breath, pain or discomfort in arms, jaw, neck, back or stomach
Stroke	Feeling dizzy or lightheaded, nausea, sweating
Tears in blood vessels supplying the brain (Cervicocephalic arterial dissection)	Sudden onset of drooping of parts of the face, weakness on one side, difficulty with speech
Thrombocytopenia	Sudden severe headache, neck pain Easy bruising and/or bleeding

Delayed autoimmune side effects

Side effect	Signs and symptoms to watch for
Thyroid disorders	Hyperthyroidism may cause sweating, weight loss, eye swelling, nervousness, and a fast heartbeat, while hypothyroidism can lead to feeling cold, weight gain, fatigue, and constipation.
Immune thrombocytopenic purpura (ITP)	Watch for red, pink, or purple spots on the skin, easy bruising, unusual bleeding (from cuts, gums, nose, or between periods), heavier or longer periods, coughing up blood, or painful/swollen joints.
Kidney problems, including nephropathies such as anti-Glomerular Basement Membrane (anti-GBM) disease	Blood in urine, swelling in legs and/or feet, coughing up blood
Autoimmune hepatitis	Be alert for nausea, vomiting, abdominal pain or swelling, fatigue, loss of appetite, yellowing of skin or eyes, dark urine, and unusual bleeding or bruising.
Haemophagocytic lymphohistiocytosis (HLH)	Seek urgent care for high fever, severe headache, stiff neck, skin rash, yellowing of skin, enlarged lymph nodes, liver or spleen, extreme fatigue, easy bruising, or recurrent infections.
Acquired haemophilia A	Watch for spontaneous bruising, nosebleeds, swollen or painful joints, and any bleeding that takes longer than usual to stop.
Thrombotic thrombocytopenic purpura (TTP)	Seek help if you notice bruising, yellow skin or eyes, dark urine, extreme tiredness, pale skin, fever, fast heartbeat, trouble breathing, confusion, seizures, stroke, stomach issues, or low blood sugar.
Adult onset still disease (AOSD)	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.
Autoimmune encephalitis (AIE)	Behavioural and/or psychiatric changes, movement disorders, short term memory loss or seizures, other symptoms which may resemble an MS relapse

Monitoring requirements

Monitoring test	When?	For how long?
Observation	Immediately after each infusion	You will be monitored for at least 2 hours, and longer if any serious side effects appear, until they are resolved.
Electrocardiogram (ECG) and vital signs, including heart rate and blood pressure (BP)	Before your infusion, baseline tests will be done, and your heart rate, blood pressure, and overall condition will be checked at least once every hour during treatment.	Once before each infusion and at least once every hour for the total duration of infusions
Blood and urine tests	Before treatment starts and once every month after finishing each treatment course	For at least 48 months after your last LEMTRADA infusion
Platelet count	Immediately after infusion on Day 3 and Day 5 of the first course, and on Day 3 of any subsequent courses	

To reduce the risk of side effects from LEMTRADA, you should adjust your diet, complete recommended vaccinations, and receive corticosteroids before the first three infusions. You will also need monitoring for side effects for at least 4 years after your last infusion.

Welcome

Your doctor has given you this Patient Guide and a Patient Alert Card to inform you about your current treatment with LEMTRADA.

This guide helps you recognize possible side effects of LEMTRADA, including reactions that may occur soon after treatment or months to years later. It explains the importance of following tests, watching for symptoms, and seeking medical help immediately.

The guide also includes definitions of medical terms and space to note your doctors' contact details, and should be reviewed with your doctor at the start of treatment and during follow-up visits.

This guide is not intended to replace any discussions you have with your doctor or the Package Leaflet for LEMTRADA which you should still read in full. Make sure you tell your doctor if you notice any of the signs or symptoms of side effects described in this guide.

Patient Alert Card

The purpose of your Patient Alert Card is to inform healthcare professionals about your LEMTRADA treatment. **You must carry your Patient Alert Card with you at all times and show it to any member of the medical team involved in your care (including for non-MS conditions) and in the event of a medical emergency.**



Introduction to LEMTRADA



What is LEMTRADA and how does it work?

LEMTRADA is for adults with relapsing-remitting multiple sclerosis that is very active or rapidly worsening despite other treatments. Clinical studies showed that patients on LEMTRADA had fewer relapses, slower disability progression, and more chances of improvement compared to those receiving frequent beta-interferon injections.

Side effects



Treatment with LEMTRADA may cause serious infections, side effects shortly after infusion (1–3 days), or delayed side effects that can appear months to years later.

Potentially serious infusion-associated side effects that usually occur during or shortly after the infusion include:

- Heart attack
- Stroke
- Tears in blood vessels supplying the brain
- Bleeding in the lung
- Thrombocytopenia

Delayed side effects that may occur with a delay of months to years after infusion:

- Thyroid disorders
- Immune thrombocytopenic purpura (ITP)
- Kidney problems, including nephropathies such as anti-Glomerular Basement Membrane disease (anti-GBM disease)
- Autoimmune hepatitis
- Haemophagocytosis lymphohistiocytosis (HLH)
- Acquired haemophilia A
- Thrombotic thrombocytopenic purpura (TTP)
- Adult onset still disease (AOSD)
- Autoimmune encephalitis (AIE)

Serious infections

If you have fever, chills, fatigue, shortness of breath, cough, chest pain, wheezing, or cough up blood, contact your doctor or go to the hospital, and make sure to inform them that you've received LEMTRADA.

Make sure you tell your doctor if you are suffering from a serious infection before you start your LEMTRADA treatment. Your doctor should delay the treatment until the infection has been resolved.

Rare brain infection (PML)

Rarely, LEMTRADA can be linked to PML, a serious brain infection. Contact your doctor immediately if you notice progressive weakness, clumsiness, vision or speech problems, or changes in thinking, memory, or personality, and keep family or caregivers informed, as they may notice symptoms you don't.

Serious side effects occurring shortly after LEMTRADA infusion

They can occur within 1–3 days or sometimes weeks later. Contact your doctor immediately if you experience trouble breathing, chest pain, facial drooping, sudden severe headache, weakness on one side, speech difficulties, neck pain, or coughing up blood.

Delayed autoimmune side effects

Treatment with LEMTRADA may increase the risk of autoimmune conditions, where the immune system attacks the body, and these can appear even years later. Regular blood and urine tests for at least 4 years are essential, even if you feel well, and you should continue to watch for symptoms beyond that period.

1. Thyroid disorders

LEMTRADA can cause thyroid disorders, including:

- Overactive thyroid gland (also called hyperthyroidism):
When the thyroid produces too much hormone
- Underactive thyroid gland (also called hypothyroidism):
When the thyroid does not produce enough hormone

Your thyroid will be checked before treatment and every 3 months for at least 4 years to detect any problems early.

What are the signs and symptoms of an overactive thyroid?

Symptoms may include:

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

What are the signs and symptoms of an underactive thyroid?

Symptoms may include:

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

What should I do if I develop a thyroid disorder?

Tell your doctor if you notice any thyroid-related symptoms. Follow their guidance for treatment, as proper management is especially important if you become pregnant, since untreated thyroid issues can harm your baby. Thyroid tests should always be done during pregnancy.

2. Immune thrombocytopenic purpura (ITP)

ITP is a condition where low platelet levels can lead to severe bleeding. It occurs in about 1% of patients on LEMTRADA but can be treated if caught early. Your doctor will check your platelets before treatment and monthly for at least 4 years, and you should watch for symptoms between tests.

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 than usual
- Heavier, longer or more frequent menstrual periods than normal
- Bleeding between your menstrual periods
- Bleeding from your gums or nose that is new or takes longer than usual to stop
- Coughing up blood

Take a look at Figure 2 which shows examples of bruises and rashes caused by ITP.

What if I develop ITP?

Early detection of ITP is crucial. Continue monthly blood tests and have your family or caregivers watch for symptoms, as prompt treatment reduces the risk of serious complications.

If you notice any of the signs or symptoms described above, contact your doctor right away to report the symptoms. If you cannot reach your doctor, seek immediate medical attention and show them your LEMTRADA Patient Alert Card.

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

Figure 2 - Examples of bruises and rashes caused by ITP

Example of arms with easy or excessive bruising.

Where on the body? Bruises may occur anywhere on your body, not just on your arms.



Example of a leg with scattered spots under the skin that are red, pink or purple. They might look like pin prick spots (petechiae) or they can be a little bigger (purpura).

Where on the body? These spots can occur anywhere on your body, not just on your legs.

Example of spots due to bleeding under the tongue.

Where on the body? This may 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.



Note: These pictures are only a guide in order to show examples of bruises or petechiae. The patient may have less severe type of bruise or petechiae than these pictures and still have ITP.

3. Kidney problems, including nephropathies such as anti-GBM disease

LEMTRADA can sometimes cause kidney problems, including anti-GBM disease, a serious autoimmune condition that can lead to kidney failure if untreated. Your doctor will monitor with blood and urine tests before treatment and monthly for at least 4 years. Be aware of symptoms and seek urgent care if they appear, as early treatment is critical.

What are the signs and symptoms of kidney problems, such as anti-GBM disease?

- Blood in the urine: your urine may be red or tea-coloured
- Swelling: in your legs or feet

In some cases, anti-GBM disease can also cause damage to your lungs, which may result in coughing up blood.

What if I develop kidney problems?

Kidney problems from LEMTRADA are usually treatable, but early detection is essential. Know the signs and symptoms and attend all regular blood and urine tests, as treatment is almost always needed.

If you notice any of the signs or symptoms described above, contact your doctor immediately to report them. If you cannot reach your doctor, make sure that you seek immediate medical attention.

4. Autoimmune hepatitis

Some people may develop liver inflammation (autoimmune hepatitis) after LEMTRADA. Contact your doctor if you notice nausea, vomiting, abdominal pain or swelling, fatigue, loss of appetite, yellow skin or eyes, dark urine, or unusual bleeding or bruising.

5. Haemophagocytic lymphohistiocytosis (HLH)

HLH is a life-threatening condition where overactive immune cells cause inflammation and damage organs like the liver and bone marrow. It can be hard to recognize at first. Contact your doctor immediately if you have high fever, severe headache, stiff neck, swollen lymph nodes, yellow skin, or a skin rash.

6. Acquired haemophilia A

Treatment with LEMTRADA may rarely cause acquired haemophilia A, a serious bleeding disorder. Contact your doctor immediately if you notice spontaneous bruising, nosebleeds, swollen or painful joints, unusual bleeding, or cuts that take longer to stop bleeding.

7. Thrombotic Thrombocytopenic Purpura (TTP)

LEMTRADA can rarely cause TTP, a serious clotting disorder. Seek urgent care for purple spots, yellow skin or eyes, dark urine, fatigue, fever, trouble breathing, confusion, seizures, stroke, stomach pain, or persistent low blood sugar.

8. Adult onset still disease (AOSD)

AOSD is a rare condition that can cause inflammation in multiple organs. Contact your doctor immediately if you have high fever lasting over a week, joint pain or stiffness, and/or a skin rash.

9. Autoimmune encephalitis (AIE)

After receiving LEMTRADA, a rare immune-mediated brain disorder may occur. Contact your doctor if you notice behavioral or psychiatric changes, movement problems, memory loss, seizures, or symptoms similar to an MS relapse.

IMPORTANT!

Since all of these delayed side effects can occur long after you received a course of treatment with LEMTRADA, it's very important that you continue to have your monthly tests (even if you are feeling well).

You must also continue to watch out for signs and symptoms for at least 48 months after your last course of treatment with LEMTRADA:

- Early detection and diagnosis may give you the best opportunity for recovery
- Carry your Patient Alert Card with you and show it to any healthcare providers who are providing you treatment (including for non-MS conditions) and in the event of a medical emergency

Other helpful information



Vaccinations

Before each LEMTRADA treatment, your doctor will check your vaccinations. If you've had a recent vaccine, you may need to wait 6 weeks before starting. Live vaccines should be avoided during and after treatment until your immune system recovers.

Fertility

You may have LEMTRADA in your body during your treatment course and for 4 months after, and it's not known if LEMTRADA will have an effect on fertility during this period. Talk to your doctor if you are or are thinking about trying to become pregnant.

Pregnancy and contraception

It's not known if LEMTRADA can harm an unborn baby. Use effective contraception during treatment and for 4 months after. Talk to your doctor if you are planning or become pregnant, and extra caution is needed if a thyroid disorder develops during pregnancy.

Breastfeeding

It's unknown if LEMTRADA passes into breast milk, so breastfeeding is not recommended during treatment and for 4 months after. Talk to your doctor to decide what's safest for you and your baby.

What other information should I tell my doctor?

Always tell your doctor about any new health problems or medicines you've taken, including prescriptions, over-the-counter drugs, vitamins, or herbal supplements, so your treatment can be managed safely.

The autoimmune conditions described in this guide may occur long after you received a course of treatment with LEMTRADA. It's very important that you continue to have your monthly tests for at least 48 months after your last treatment course, even if you're feeling well.

How to reach your doctors



To make it easier to contact your healthcare team, write their contact details in the chart below.

Name of doctor or MS nurse:.....
Phone number:.....
Email address:.....

Name of doctor or MS nurse:.....
Phone number:.....
Email address:.....

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