LEMTRADA®
alemtuzumab 12mg IV

Patient Guide to LEMTRADA®

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

This Guide is to be carefully reviewed with your doctor when you're first prescribed LEMTRADA® and on a regular basis at follow-up visits.

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.

For full prescribing information refer to the professional information approved by the medicines regulatory authority.

To report an adverse event:

- Use the Med Safety App [accessible from the Apple store (for iOS devices) and Google Play (for android devices)] via https://medsafety.sahpra.org.za/ **alternatively,**
- Complete the ADR reporting form accessible via the SAHPRA website at www.sahpra.org.za and email it to adr@sahpra.org.za **and**
- Adverse events should also be reported to the Pharmacovigilance Department of Sanofi by emailing za.drugsafety@sanofi.com or calling 011 256 3700

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Section 1. Executive summary

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

This section is an abbreviated guide – please refer to the full guide which follows (section 2-8) for more information.

This guide is not intended to replace the Patient Information Leaflet or discussions you have with your doctor or other healthcare professionals who are treating you with LEMTRADA®.

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LEMTRADA® is a prescription medicine used to treat adults with relapsing remitting multiple sclerosis (MS). LEMTRADA® should be used in patients with highly active disease, despite treatment with at least one disease modifying therapy, or in patients with rapidly evolving severe MS.

Receiving LEMTRADA® can put you at risk of experiencing serious side effects that may occur within 1-3 days of infusion, or delayed autoimmune side effects which can occur months to years after infusion.

Early identification of these side effects is vital, because a delay in diagnosis and treatment can increase the risk of complications. This is why it is so important to remain vigilant and immediately report any signs or symptoms of these conditions to your doctor.

It is also important to inform your relatives or caregivers about your treatment, since they may notice symptoms that you are not aware of.

See the following tables for a summary of signs and symptoms to look out for.

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, swollen glands and abdominal pain
Brain infection (Progressive Multifocal Leukoencephalopathy [PML])	• Progressive weakness or clumsiness of limbs, disturbance of vision, speech difficulties or changes in thinking, memory, and orientation leading to confusion and personality changes.

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Side effects occurring shortly after LEMTRADA® infusion

Side effect	Signs and symptoms to watch for
Infusion- Associated Reactions (IARs)	• Most patients treated with LEMTRADA® will experience side effects (such as headache, fever, feeling sick, hives, itching, reddening of the face and neck, feeling tired, nausea, increased heart rate, indigestion, chills, chest discomfort, pain, dizziness, altered taste, difficulty sleeping, difficulty breathing or shortness of breath, rash over your body or low blood pressure) at the time of the infusion or within 24 hours after the infusion. To try to reduce infusion reactions, your doctor will give you other medicine(s). Should your general health worsen or if you experience any untoward effects while you are receiving LEMTRADA®, or after having received LEMTRADA® immediately inform your Healthcare Professional.

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 up blood • Chest pain or discomfort, shortness of breath, pain or discomfort in arms, jaw, neck,back or stomach • Feeling dizzy or lightheaded, nausea, sweating • Sudden onset of drooping a parts of the face, weakness on one side, difficulty with speech • Sudden severe headache, neck pain • Easy bruising and/or bleeding
Bleeding in the lung	
Stroke	
Tears in blood vessels supplying the brain	
Thrombocytopenia	

Delayed autoimmune side effects

Side effect	Signs and symptoms to watch for
Thyroid disorders	• Hyperthyroidism (overactive thyroid gland): excessive sweating, unexplained weight loss, eye swelling, nervousness, fast heartbeat • Hypothyroidism (underactive thyroid gland): feeling cold, unexplained weight gain, worsening tiredness, newly occurring constipation

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Delayed autoimmune side effects continued

Side effect	Signs and symptoms to watch for
Immune thrombocytopenic purpura (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 • Painful or swollen joints
Kidney problems, including nephropathies such as anti- Glomerular Basement Membrane (anti-GBM)	• Blood in urine, swelling in legs and/or feet, coughing up blood
Autoimmune hepatitis	• Unexplained nausea, vomiting, abdominal pain and/or swelling, fatigue, loss of appetite, yellowing of skin or eyes and/or dark coloured urine, bleeding or bruising more easily than normal
Haemophagocytic lymphohistiocytosis (HLH)	• Unexplained high fever, severe headache, stiff neck, lymph node enlargement, yellow skin, skin rash
Acquired haemophilia A	• Spontaneous bruising, nose bleeds, painful or swollen joints, other types of bleeding, bleeding from a cut that may take longer than usual to stop
Other autoimmune side effects	• You may experience additional autoimmune conditions such as cytopenias involving your red or white blood cells. This may be diagnosed from the blood test that you will be having regularly after LEMTRADA® treatment
Thrombotic thrombocytopenic purpura (TTP)	• Bruising under the skin or inside the mouth, yellowing of the skin and eyes; and/or dark coloured urine, low amount of urine, red pinpoint dots with or without unexplained extreme tiredness, very pale skin, fever, fast heartbeat or short of breath, headache, speech changes, confusion, coma, stroke, seizure, stomach area pain, nausea, vomiting, or diarrhoea, vision changes, persistent low sugar symptoms

General

To minimise the risk of side effects associated with LEMTRADA®, it is advised that you make changes to your diet and complete the recommended vaccination programme 6 weeks prior to starting your LEMTRADA® treatment. Your doctor will also give you corticosteroids right before the first 3 infusions of each course to reduce your risk of infusion-associated reactions.

You will need to be monitored for side effects during treatment, between treatment courses and for at least 4 years (48 months) after your last

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LEMTRADA® infusion. See the table below for a summary of monitoring tests that are required when you are prescribed with LEMTRADA®.

Monitoring requirements

Monitoring test	When?	For how long?
Observation	• Immediately after each infusion	• For at least 2 hours. If you start to display signs and/or symptoms of serious side effects, you will be monitored until they are resolved
Electrocardiogram (ECG) and vital signs, including heart rate and blood pressure (BP)	• Baseline tests right before infusion • Frequent monitoring of heart rate, BP and overall clinical status at least once every hour during your infusion	• 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	

Pregnancy and breastfeeding

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you receive LEMTRADA®. LEMTRADA® should not be administered during pregnancy.

Women who are able to conceive should use effective contraceptive methods during each treatment course with LEMTRADA® and for 4 months after each course of treatment.

Tell your doctor immediately if you become pregnant during your treatment course or within 4 months of receiving a treatment course.

If you become pregnant after treatment with LEMTRADA® and experience a thyroid disorder during pregnancy, extra caution is needed. Thyroid disorders could be harmful to the baby.

It is recommended that you do not breastfeed during each course of treatment with LEMTRADA® and for 4 months after each treatment course. Talk to your doctor if you are planning to breastfeed your baby. Your doctor will advise you what is right for you and your baby.

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Welcome

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

This guide has been created to support you in identifying the symptoms of the side effects that have been reported with the use of LEMTRADA®, as well as outlining the importance of being compliant with testing, being vigilant for symptoms and seeking immediate medical attention should they occur.

Side effects that may occur shortly after LEMTRADA® infusion (within 1-3 days of infusion) or later, and include infections and other serious reactions. Delayed side effects include autoimmune disorders that can develop with a delay of months to years after treatment with LEMTRADA®; these are conditions in which your immune system mistakenly attacks your body.

There's also a section in this guide that will help you to understand some of the medical terms used in this document, and a section to keep a note of the contact details of all the doctors you may be seeing for your healthcare. This includes the doctor treating your multiple sclerosis (MS) as well as any other doctor you see on a regular basis.

This Patient Guide is to be carefully reviewed with your doctor when you are first prescribed LEMTRADA® and on a regular basis at follow-up visits.

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This guide is not intended to replace any discussions you have with your doctor or the Patient Information 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.

Copies of these materials are available and must be distributed to you when your Doctor considers you for LEMTRADA® treatment. You can also request these patient education materials from the Patient Support Program (PSP) provider.

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.**

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Section 2. Introduction to LEMTRADA®

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What is LEMTRADA® and how does it work?

LEMTRADA® is a prescription medicine used to treat adults with relapsing remitting multiple sclerosis (MS). LEMTRADA® is used if your MS is highly active despite being treated with at least one other medicine for MS or if your MS is rapidly evolving.

LEMTRADA® adjusts your immune system to limit its attacks on your nervous system. After treatment with LEMTRADA®, you may be at risk of developing side effects. It is important that you understand what these risks are and how to monitor for them.

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Section 3. Overview of LEMTRADA® treatment

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How is LEMTRADA® given?

LEMTRADA® is given to you by infusion using a needle through which it will be delivered into your blood stream. LEMTRADA® is given in at least 2 courses of treatment. You will receive the first course as one infusion per day for 5 days in a row. Each infusion is given over at least a 4-hour period. Then, one year later, you will receive the next course as one infusion per day for 3 days in a row. You may need additional treatment courses in the years after your initial 2 courses.

You will need to be regularly monitored for side effects during treatment, between courses and for at least 48 months after your last infusion of LEMTRADA® (see 'Will I need to have any tests done after treatment with LEMTRADA®?')

Do I need to do anything before I can be treated with LEMTRADA®?

To make sure LEMTRADA® is the right therapy for you, your doctor needs some information. Therefore, you need to inform your doctor about:

- All medicines that you are taking
- If you are suffering from any infection including HIV, tuberculosis, hepatitis B virus (HBV), or hepatitis C virus (HCV)
- If you have been previously diagnosed with cancer
- If you have been diagnosed with abnormalities of the cervix (the neck of the womb)
- If you are pregnant or plan to become pregnant very soon or are breastfeeding
- If you are suffering from high blood pressure
- If you have suffered in the past from heart attack or chest pain, tears in blood vessels, stroke or a bleeding disorder
- If you have other autoimmune conditions (besides MS)
- Tell your doctor about any allergies you may have, including any allergies to medicines and medicinal ingredients

Your doctor will also carry out checks and offer treatment and advice before starting your infusion course that may help to reduce your risk of infusion-associated reactions and infections after your LEMTRADA® treatment. These include:

- Vaccination check
  - If you have not yet done so, you may be advised to complete your local vaccination programme at least 6 weeks before starting treatment
  - You may also be advised to receive additional vaccinations before you start treatment
- Tuberculosis screening and treatment
  - Your doctor will screen for active and inactive ("latent") tuberculosis prior to starting, between courses, as well as after LEMTRADA® treatment
  - If required, your doctor may prescribe appropriate treatment to treat an active tuberculosis infection, or prophylactic treatment to prevent tuberculosis infection if you present with latent tuberculosis, according to the relevant South African guidelines, before the initiation or re-administration of LEMTRADA® treatment
  - if you display symptoms of tuberculosis (e.g. coughing up blood, night sweats, weight loss) or you have been in contact with someone who has tuberculosis, please contact your doctor to arrange a screening
- Dietary recommendation
  - To reduce your risk of infections after treatment, your doctor will recommend that you avoid uncooked or undercooked meats, soft cheeses and unpasteurised dairy products two weeks prior to, during and for at least 1 month after your LEMTRADA® infusion
  - Ask your doctor about appropriate steps to avoid food that has the potential to be contaminated with listeria
- Pre-treatment
  - To reduce your risk of infusion-associated reactions, your doctor will give you corticosteroid treatment before the first 3 infusions of each of your LEMTRADA® treatment courses
  - Other treatments to limit these reactions can also be given before infusions
- Vital signs check
  - Your doctor will check your vital signs, including blood pressure and heart rate, before you start your treatment

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- Blood and urine tests
  - Will be performed before you start your LEMTRADA® treatment
- Infection prevention
  - Your doctor will screen you for various infections
  - Your doctor will prescribe an oral anti-herpes prophylaxis on Day 1 of treatment and continue for at least 1 month following each course of treatment

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

Treatment with LEMTRADA® may increase the risk of autoimmune conditions (conditions in which your immune system mistakenly attacks your body). These are delayed side effects which can occur many years after your treatment (described in Section 4 of this guide). You will therefore need to commit to monthly monitoring, undertaking blood and urine tests in between treatment courses and for at least 48 months after your last LEMTRADA® infusion. Your doctor will check the results of these tests to see if you have developed any side effect(s).

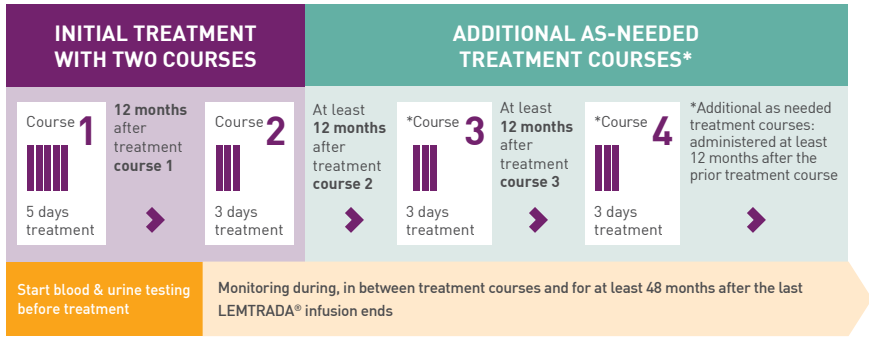
It is very important that you continue to have these checks for at least 48 months after your last course of treatment with LEMTRADA®, even if you are feeling well (this means that you have no symptoms of side effects) and your MS symptoms are under control. Side effects can even occur years after your last course of treatment with LEMTRADA®, when your monthly checks are no longer required. In some cases, side effects can be life-threatening, so it is very important that you continue to be checked and keep an eye out for symptoms. By doing so, any problems will most likely be detected early and treatment can start right away.

You and your doctor will work together to make sure that these tests are done, and plan them around your day-to-day life. If you are a woman, it is also important to avoid urine testing during your menstrual periods as this may give a false result.

To help you better understand the timescale of possible treatment side effects and the length of required follow-up, see Figure 1 and Table 1 opposite.

Your doctor should have discussed delayed infusion-associated reactions that can occur after an infusion has been completed. Inform your doctor if you have any symptoms following your infusion and seek immediate medical care. Infusion-associated reactions can occur at the time of infusion and/or up to several days after infusion.

Figure 1 – Duration of the effects of treatment and the length of required follow-up



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

Table 1 – Summary of monitoring tests

Monitoring test	When?	For how long?
Observation	• Immediately after each infusion	• For at least 2 hours. If you start to display signs and/ or symptoms of serious side effects, you will be monitored until they are resolved
Electrocardiogram (ECG) and vital signs, including heart rate and BP	• Baseline tests right before infusion • Frequent monitoring of heart rate, BP and overall clinical status at least once every hour during your infusion	• 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	• Monthly, 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	

There are tools available to help you plan and remember your monitoring schedule. Refer to Section 6 of this guide, 'Planning your monitoring schedule'

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Section 4.
Side effects

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As mentioned earlier in this guide, treatment with LEMTRADA® can put you at risk of:

- Contracting serious infections,
- Experiencing side effects that mainly occur during or shortly after the LEMTRADA® infusion (within 1-3 days) or later, or
- Developing delayed side effects that can occur months to years after treatment with LEMTRADA®.

Potentially serious infusion-associated side effects that may occur during or soon after an infusion include:

- Heart attack
- Stroke
- Tears in blood vessels supplying the brain
- Bleeding in the lung
- Thrombocytopenia (low blood platelet count)

Side effects that may occur with a delay of months to years after infusion include:

- Thyroid disorders
- Immune thrombocytopenic purpura (ITP)
- Kidney problems, including nephropathies such as anti-Glomerular Basement Membrane disease (anti-GBM disease)
- Autoimmune hepatitis
- Haemophagocytic lymphohistiocytosis (HLH)
- Acquired haemophilia A
- Cytopenias (low blood cell counts)
- Thrombotic thrombocytopenic purpura (TTP)

Early identification of these conditions is vital, as delays in diagnosis and treatment increases the risk of complications. This is why it is so important to recognise and immediately report any signs or symptoms of these conditions to your doctor or go to the hospital.

In the following sections, you will learn more about each of these side effects, including the signs and symptoms that you may experience with them and what to do if they happen.

Serious infections

Receiving treatment with LEMTRADA® can put you at risk of getting a serious infection. If you develop symptoms of a serious infection such as persistent fever, chills, fatigue, swollen glands, abdominal pains or not feeling well, you may have to go to hospital for treatment.

You should also report symptoms like shortness of breath, night sweats, cough, wheezing, chest pain or tightness and coughing up blood to your doctor, as these may be symptoms of tuberculosis or caused by pneumonitis.

When attending hospital with any symptoms of infection, it's important that you tell doctors that you have received treatment with 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)

There have been cases of a rare brain infection called PML (progressive multifocal leukoencephalopathy) in patients who have been given LEMTRADA®. These patients had other risk factors - specifically prior treatment with MS products associated with PML.

PML symptoms may be similar to a relapse of MS. You should contact your doctor immediately if you develop any symptoms like progressive weakness or clumsiness of limbs, disturbance of vision, speech difficulties or changes in thinking, memory, and orientation leading to confusion or personality changes.

It is important to inform your relatives or caregivers about your treatment, since they may notice symptoms that you are not aware of.

Serious side effects occurring shortly after LEMTRADA® infusion

When prescribed LEMTRADA®, you can be at risk of developing serious side effects that occur during or shortly after infusion. In the majority of cases, onset of these reactions is within 1-3 days of LEMTRADA® infusion, but some may occur weeks later. Tell your doctor right away if you develop any of the following symptoms: trouble breathing, chest pain, facial drooping, sudden severe headache, weakness on one side of the body, difficulty with speech, neck pain or coughing up blood.

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Delayed autoimmune side effects

Treatment with LEMTRADA® may increase the risk of autoimmune conditions. These are conditions in which your immune system mistakenly attacks your body and these can occur many years after treatment. Therefore, regular blood and urine tests are needed until at least 48 months after your last infusion. Testing is needed even if you are feeling well and your MS symptoms are under control. In addition, these conditions may occur beyond 48 months, therefore, you must continue to look for signs and symptoms, even after you no longer need to have monthly blood and urine tests.

1. Thyroid disorders

The thyroid is a gland in the lower part of the neck that produces hormones which are involved in several processes throughout your body. In some people, the immune system mistakenly attacks the cells of the thyroid gland (autoimmune thyroid condition). This affects its ability to make and control the level of hormones that are important for metabolism.

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 function will be checked before you start your treatment with LEMTRADA®, and every 3 months after each treatment course and for at least 48 months after your last infusion. This blood test will help your doctor to detect any thyroid disorders early.

To report an adverse event:
- Use the Med Safety App (accessible from the Apple store (for iOS devices) and Google Play (for android devices)) via https://medsafety.sahpra.org.za/ **alternatively,**
- Complete the ADR reporting form accessible via the SAHPRA website at www.sahpra.org.za and email it to adr@sahpra.org.za **and**
- Adverse events should also be reported to the Pharmacovigilance Department of Sanofi by emailing za.drugsafety@sanofi.com or calling 011 256 3700

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 experience any of the symptoms above.

Depending on the type of thyroid disorder you are experiencing, your doctor will decide which treatment is best for you. It is very important that you follow your doctor's recommendations to be sure that you benefit most from your treatment.

If you develop a thyroid disorder after receiving LEMTRADA®, it is very important that you're properly treated for it, especially if you are female and become pregnant. Having an untreated thyroid disorder could harm your baby before it is born or after birth. Thyroid function tests must always be taken in case of pregnancy.

2. Immune thrombocytopenic purpura (ITP)

ITP is a condition which results in a low number of platelets in the blood. Serious ITP occurs in approximately 1% of patients taking LEMTRADA®. Platelets are necessary for normal blood clotting. As a result, ITP can cause severe bleeding. It is treatable if detected promptly, but if left untreated it can lead to serious health problems and may be fatal.

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A blood test will help your doctor monitor for changes in your platelet count, and catch ITP early should it arise. Therefore, your doctor will run a blood test before starting your LEMTRADA® treatment, and on a monthly basis in between treatment courses and for at least 48 months following your last treatment course.

It is important to note that ITP can start quickly and may occur in between the blood tests. It is therefore essential that you remain vigilant for signs and symptoms.

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?

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 tests, which could detect a problem before you notice any symptoms. It is also important that you, your family members and/or caregivers are watching out for the signs and symptoms described in this guide. Delaying treatment of ITP increases the chance of more serious problems.

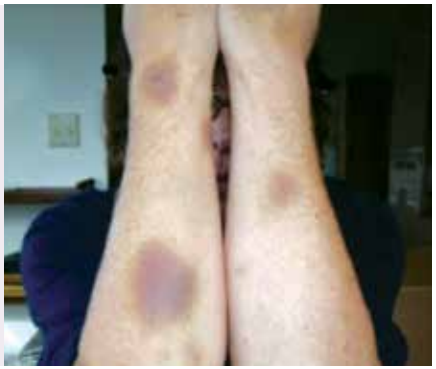
If you notice any of the signs or symptoms described above, contact your doctor right away to report the symptoms. If you cannot reach your doctor, seek immediate medical attention and show them your LEMTRADA® Patient Alert Card.

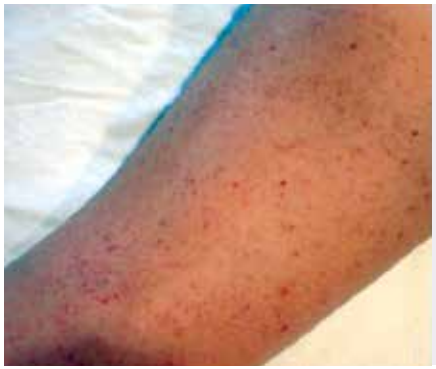
If detected early, ITP is usually treatable. If you develop ITP, you and your doctor will decide which treatment is best for you.

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.



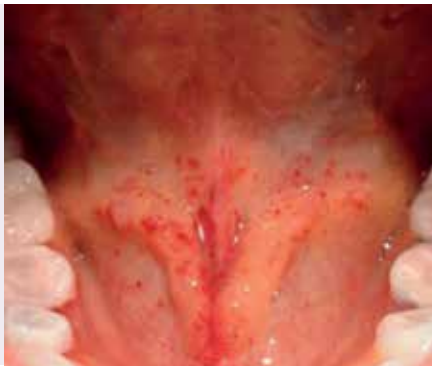


Example of a leg with scattered spots under the skin that are red, pink or purple. They might look like pin pricks (petechiae) or they can be a little bigger (purpura).

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. You may have less severe bruising or petechiae than these pictures and still have ITP.

To report an adverse event:
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- Adverse events should also be reported to the Pharmacovigilance Department of Sanofi by emailing za.drugsafety@sanofi.com or calling 011 256 3700

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

LEMTRADA® can sometimes cause kidney problems, including 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. If left untreated, anti-GBM disease can cause kidney failure that requires chronic dialysis or transplantation, and may eventually lead to death.

Blood and urine tests will help your doctor to monitor for signs of kidney disease and catch any problems early should they arise. Your doctor will run blood and urine tests before starting LEMTRADA®, and on a monthly basis that will continue between each treatment course and for at least 48 months after your last treatment course. If you are a woman, it is also important to avoid urine testing during your menstrual period as this may give a false result.

You should be aware of the signs and symptoms of kidney problems and report them to your doctor if you spot any of them.

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 are usually treatable. However, it's best to begin treatment as early as possible. It's important that you are familiar with the signs and symptoms of kidney problems and anti-GBM disease, and attend your regular blood and urine tests. Kidney problems will almost always need treatment.

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

To report an adverse event:
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- Adverse events should also be reported to the Pharmacovigilance Department of Sanofi by emailing za.drugsafety@sanofi.com or calling 011 256 3700

4. Autoimmune hepatitis

Some people have developed liver inflammation, also known as autoimmune hepatitis, after receiving LEMTRADA®. If you experience unexplained nausea, vomiting, abdominal pain and/or swelling, fatigue, loss of appetite, yellow skin or eyes and/or dark urine, or bleeding or bruising more easily than normal, report this to your doctor.

5. Haemophagocytic lymphohistiocytosis (HLH)

HLH is a life-threatening condition that occurs when specific immune cells become overactive, causing too much inflammation. Ordinarily, these cells should destroy infected or damaged cells of the body, but in HLH, they start to damage your own tissues and organs, including the liver and bone marrow where blood is made. HLH can be challenging to diagnose because the initial symptoms may mimic other problems such as common infections. If you experience unexplained high fever, severe headache, stiff neck, lymph node enlargement (swollen glands), yellow skin, bruising, or skin rash you must call your doctor right away to report the symptoms.

6. Acquired haemophilia A

When treated with LEMTRADA® it is possible that you may develop a disorder called acquired haemophilia A. This is a bleeding disorder caused by antibodies that work against a protein needed for normal clotting of the blood, and can cause you to develop complications associated with abnormal, uncontrolled bleeding into the muscles, skin and soft tissue and during surgery or following trauma. This condition must be diagnosed and treated immediately. If you experience spontaneous bruising, nose bleeds, painful or swollen joints, other types of bleeding, or bleeding from a cut that may take longer than usual to stop, you must call your doctor right away to report the symptoms.

7. Cytopenias (low blood cell counts)

When treated with LEMTRADA®, it is possible that you may experience autoimmune conditions involving red blood cells or white blood cells. These can be diagnosed from the blood tests that you will be having regularly after LEMTRADA® treatment. If you develop one of these conditions your doctor will tell you and take appropriate measures to treat it.

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8. Thrombotic Thrombocytopenic Purpura (TTP)

TTP is a disease where blood clots form inside blood vessels and can occur with LEMTRADA®, TTP can occur all over the body and it needs to be treated in a hospital right away, because it can cause death. Get medical help right away if you have any of these symptoms: purplish spots on the skin or in the mouth, yellow skin and eyes and/or dark urine, tiredness or weakness, very pale skin, fever, fast heartbeat or short of breath, headache and speech changes, confusion, coma, stroke, seizure, stomach area pain, nausea, vomiting or diarrhea, vision changes, persistent low sugar symptom.

IMPORTANT!

Since all of these delayed side effects can 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 out for signs and symptoms during, between treatment courses and 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

Not all side effects reported for LEMTRADA® are included in this Patient Guide. Should your general health worsen or if you experience any untoward effects while you are receiving LEMTRADA®, please consult your doctor, pharmacist or other healthcare professional for advice.

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- Adverse events should also be reported to the Pharmacovigilance Department of Sanofi by emailing za.drugsafety@sanofi.com or calling 011 256 3700

Section 5.
Other helpful information

To report an adverse event:
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Vaccinations

Before receiving each course of treatment with LEMTRADA®, your doctor will check that you are up to date with your vaccinations. If you need a vaccination, you will have to wait for 6 weeks after vaccination to start your LEMTRADA® treatment. Tell your doctor if you have had a vaccination within the last 6 weeks.

Fertility

You may have LEMTRADA® in your body during your treatment course and for 4 months after, and it is not known if LEMTRADA® will have an effect on fertility during this period. Talk to your doctor if you think you may be pregnant or are planning to become pregnant.

Pregnancy and contraception

It is not known if LEMTRADA® could harm an unborn child. Therefore LEMTRADA® should not be administered during pregnancy. You should use effective contraception during each treatment course with LEMTRADA® and for 4 months after each course of treatment to ensure there is no LEMTRADA® left in your body before you conceive a child. Make sure you tell your doctor if you are planning to become pregnant.

If you are already pregnant or plan to become pregnant soon, you should ask your doctor for advice before starting treatment with LEMTRADA®.

Tell your doctor right away if you become pregnant during your treatment course or within 4 months of receiving a LEMTRADA® infusion.

If you become pregnant after treatment with LEMTRADA® and experience a thyroid disorder during pregnancy, extra caution is needed as thyroid disorders can be harmful to an unborn baby.

To report an adverse event:
- Use the Med Safety App (accessible from the Apple store (for iOS devices) and Google Play (for android devices)) via https://medsafety.sahpra.org.za/ **alternatively,**
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Breastfeeding

It is unknown if LEMTRADA® can be transferred to a baby through breast milk, but it is a possibility. It is therefore recommended that you do not breastfeed during any course of treatment and for 4 months after each LEMTRADA® treatment course. You should talk to your doctor if you are planning to breastfeed. Your doctor will advise you on what is right for you and your baby.

What other information should I tell my doctor?

Be sure to tell your doctor or healthcare team about any new health problems you have developed and any new medicines you have taken since your last appointment. Those medicines may include prescription and non-prescription medicines, vitamins, and herbal supplements. It is important for your doctor to know this to manage your treatment.

To report an adverse event:
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Section 6. Planning your monitoring schedule

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

The following tools can help you remember your monitoring tests. You can use as many, or as few, of them as you like.

- **Phone call, SMS and/or email reminders:**
  If you register with the Patient Support Program (PSP) you will receive communications from a PSP Nurse aimed to educate you and importantly to remind you to go for monthly blood and urine monitoring.
- **Calendar:**
  A calendar is available for you to mark your test dates. This can be sent to you. You can mark the date of your test each month, to remind you it is coming up. Should you need a replacement at any time you can request this through the PSP.

You will be required to sign a patient consent form to receive services from the PSP provider. Your doctor will provide you with the consent form.

These services are offered through a third party, who will collect and process your personal data in accordance with appropriate data protection legislation. Your personal data will be stored securely and will not be shared with others as per the consent form signed when registering with the Patient Support Program (PSP). Again, these services are optional and you can opt in or out at any time.

Don't forget, should you experience any of the events described in this guide, early detection and diagnosis will give you the best opportunity for recovery.

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Section 7. Helpful terms to know

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Acquired haemophilia A: A disorder that occurs in people with no personal or family history of a bleeding disorder. In acquired haemophilia A, the body produces antibodies that attack clotting factors, specialised proteins required for the blood to clot normally. Affected individuals develop complications associated with abnormal, uncontrolled bleeding into the muscles, skin and soft tissue and spontaneously, during surgery or following trauma.

Anti-Glomerular Basement Membrane disease (anti-GBM): A disease caused by the immune system targeting the kidneys and in some cases, the lungs. The kidneys are damaged and do not work properly, or completely fail. As a result you may require dialysis and/or kidney transplantation. If detected promptly it is treatable, but if untreated, it can lead to death.

Autoimmune conditions/disorders: The immune system usually protects the body from bacteria, viruses, and other harmful agents. When the immune system turns against a person's own cells and organs, this is known as an autoimmune disorder or condition. In MS, the immune system mistakes components of the brain or spinal cord as foreign and damages them. Other autoimmune conditions can damage other organs or blood cells.

Autoimmune hepatitis: A certain type of liver inflammation that occurs when the body's immune system, which ordinarily attacks pathogens (e.g. viruses and bacteria), targets the liver. This attack on your liver can lead to inflammation and cause serious damage to liver cells. 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.

Autoimmune thyroid disorder: A disorder that occurs when the immune system mistakenly attacks the thyroid gland. Autoimmune thyroid disorders are treatable. They can come in different types:

- Hyperthyroidism: when the thyroid produces too much hormones
- Hypothyroidism: when the thyroid does not produce enough hormones

Dialysis: A process for removing excess water and waste products from the blood when the kidneys are not working properly.

Haemophagocytic lymphohistiocytosis (HLH): A life-threatening condition that occurs when certain types of immune cells don't work properly. These cells become overactive, causing too much inflammation. In HLH, the immune system begins to damage your own tissues and organs, including the liver and bone marrow where blood is made. HLH can be challenging to diagnose because the initial symptoms may mimic other conditions such as common infections. Signs and symptoms of HLH may include: persistent fever, skin rash, swollen glands.

Immune system: Your body's defence system against infections, foreign substances, and abnormal cells.

Infusion: A method of administering a treatment whereby a solution (a liquid containing a medicine) is slowly passed into a vein through a needle.

ITP (immune thrombocytopenic purpura): A condition which results in a low number of platelets in the blood. Platelets are necessary for normal blood clotting, therefore ITP can cause severe bleeding. ITP is treatable if detected promptly, but if left untreated it can lead to serious health problems and may be fatal.

Platelets: Platelets travel in the bloodstream and are necessary for normal blood clotting. They help stop bleeding by sticking together to form a clot, helping to seal small cuts or breaks in the skin.

Progressive Multifocal Leukoencephalopathy (PML): A rare infection of the brain. You should contact your doctor immediately if you develop any symptoms like progressive weakness or clumsiness of limbs, disturbance of vision, speech difficulties or changes in thinking, memory, and orientation leading to confusion and personality changes.

Thyroid: A gland found in the lower part of your neck. This gland produces hormones that are important for regulating metabolism.

Thrombotic Thrombocytopenic purpura (TTP): A blood clotting disease where blood clots form in blood vessels and can occur anywhere in the body.

To report an adverse event:
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Section 8. How to reach your doctors

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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:.....

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

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To report an adverse event:

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For full prescribing information refer to the professional information approved by the medicines regulatory authority.

S4 **LEMTRADA®** (Concentrate for solution for infusion) **COMPOSITION:** Each vial contains 12 mg/1,2 mL alemtuzumab (10 mg/mL). **REGISTRATION NUMBER:** 48/30.1/0263. **NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:** sanofi-aventis south africa (pty) ltd., Reg. no.: 1996/010381/07, Floor 5, Building I, Hertford Office Park, 90 Bekker Road, Midrand, 2196. Tel: 011 256 3700.

MAT-ZA-2200233 - 1.0 - 04/2022

LEMTRADA® alemtuzumab 12mg IV

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