

LEMTRADA®
alemtuzumab^{12mg}_{IV}

LEMTRADA® MONITORING CALENDAR



ms one to one™
Supporting you every day

This patient calendar is for adults who have been prescribed LEMTRADA®.
The MS One to One™ support programme has been created and funded by Sanofi
and is a post-prescription service for patients prescribed LEMTRADA®.

sanofi



This calendar will help you keep track of appointments for the required monitoring between and after your infusion courses.

WELCOME

Welcome to your LEMTRADA® monitoring calendar

Your doctor has prescribed a medicine for your multiple sclerosis (MS) called LEMTRADA® (alemtuzumab).

LEMTRADA® does not cure MS, but it can slow down or reverse some of the signs and symptoms of MS and can reduce the number of relapses.

Since side effects of LEMTRADA®, and in particular the delayed onset autoimmune conditions, could occur after you receive a course of infusions, it is very important that you continue to monitor the way your body is responding to treatment even if you are feeling well.



You can find more information about your treatment in your LEMTRADA® Patient Guide or the Patient Information Leaflet. Please speak to your treating neurologist/MS team should you have any concerns or questions about your treatment.

PERSONAL DETAILS

Name:

Address:

Telephone:

Who to contact
in an emergency:

General practitioner name:

Address:

MS neurologist name:

MS nurse name:

Phlebotomist name:

Other:

Hospital contact details:

Notes:

CALENDAR AND RESULTS

In the following pages, you can write down your appointment dates, times and places over the course of your treatment journey. Keep track of the tests you have done by checking them off when you have completed them.

At the bottom of each yearly calendar page there is a section to make notes and write down any questions or thoughts that you may have and want to discuss with your MS team.

Please note that this calendar includes 5 years of monitoring space - the year between your first and second treatment courses and at least 48 months (4 years) afterwards. However, if you require additional treatment courses, ensure you continue monitoring for at least 48 months after your last infusion.

Remember to carry your **Patient Alert Card** with you and show it to any healthcare professionals who are providing you with treatment (including treatment for non-MS conditions) or in the event of a medical emergency, as this will alert them to the fact that you have received treatment with LEMTRADA® for your MS. Please note that if you are in a medical emergency or are treated by any other healthcare professional, you need to notify your neurologist/MS team of this.

Monitoring after 1st treatment course

YEAR 1

	Treatment	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6
Month							
Appointment							
Tip: Set up electronic reminders of your appointment dates	Date Time Place						
Nurse/phlebotomist/neurologist initials							
*Full blood count (FBC) with differential	<input type="checkbox"/>						
*Serum creatinine	<input type="checkbox"/>						
*Serum transaminases (AST and ALT)	<input type="checkbox"/>						
*Thyroid Function Tests (TFTs)	<input type="checkbox"/>			<input type="checkbox"/>			<input type="checkbox"/>
*Urinalysis with microscopy	<input type="checkbox"/>						
TB screening (refer to page 34 for more details)							

Notes:

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*Further explanation of these terms can be found at the end of this booklet

Monitoring after 1st treatment course

YEAR 1

	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12
Month						
Appointment						
Tip: Set up electronic reminders of your appointment dates	Date	Time	Place			
Nurse/phlebotomist/neurologist initials						
*Full blood count (FBC) with differential	<input type="checkbox"/>					
*Serum creatinine	<input type="checkbox"/>					
*Serum transaminases (AST and ALT)	<input type="checkbox"/>					
*Thyroid Function Tests (TFTs)			<input type="checkbox"/>			<input type="checkbox"/>
*Urinalysis with microscopy	<input type="checkbox"/>					
TB screening (refer to page 34 for more details)						

Yearly cervical human papilloma virus (HPV)
screening - female only



Notes:

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Monitoring after 2nd treatment course

YEAR 2

Continue monitoring for at least 48 months after last infusion

	Treatment	Month 13	Month 14	Month 15	Month 16	Month 17	Month 18
Month							
Appointment							
Tip: Set up electronic reminders of your appointment dates	Date Time Place
Nurse/phlebotomist/neurologist initials							
*Full blood count (FBC) with differential	<input type="checkbox"/>						
*Serum creatinine	<input type="checkbox"/>						
*Serum transaminases (AST and ALT)	<input type="checkbox"/>						
*Thyroid Function Tests (TFTs)	<input type="checkbox"/>			<input type="checkbox"/>			<input type="checkbox"/>
*Urinalysis with microscopy	<input type="checkbox"/>						
TB screening (refer to page 34 for more details)							

Notes:

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Monitoring after 2nd treatment course

YEAR 2

Continue monitoring for at least 48 months after last infusion

	Month 19	Month 20	Month 21	Month 22	Month 23	Month 24
Month						
Appointment	Date					
Tip: Set up electronic reminders of your appointment dates	Time					
	Place					
Nurse/phlebotomist/neurologist initials						
*Full blood count (FBC) with differential	<input type="checkbox"/>					
*Serum creatinine	<input type="checkbox"/>					
*Serum transaminases (AST and ALT)	<input type="checkbox"/>					
*Thyroid Function Tests (TFTs)			<input type="checkbox"/>			<input type="checkbox"/>
*Urinalysis with microscopy	<input type="checkbox"/>					
TB screening (refer to page 34 for more details)						

Yearly cervical human papilloma virus (HPV)
screening - female only



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Monitoring after 2nd treatment course

YEAR 3

	Month 25	Month 26	Month 27	Month 28	Month 29	Month 30
Month						
Appointment	Date					
Tip: Set up electronic reminders of your appointment dates	Time					
	Place					
Nurse/phlebotomist/neurologist initials						
*Full blood count (FBC) with differential	<input type="checkbox"/>					
*Serum creatinine	<input type="checkbox"/>					
*Serum transaminases (AST and ALT)	<input type="checkbox"/>					
*Thyroid Function Tests (TFTs)			<input type="checkbox"/>			<input type="checkbox"/>
*Urinalysis with microscopy	<input type="checkbox"/>					
TB screening (refer to page 34 for more details)						

Notes:

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Continue monitoring for at least 48 months after last infusion

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Monitoring after 2nd treatment course

YEAR 3

Continue monitoring for at least 48 months after last infusion

	Month 31	Month 32	Month 33	Month 34	Month 35	Month 36
Month						
Appointment	Date					
Tip: Set up electronic reminders of your appointment dates	Time					
	Place					
Nurse/phlebotomist/neurologist initials						
*Full blood count (FBC) with differential	<input type="checkbox"/>					
*Serum creatinine	<input type="checkbox"/>					
*Serum transaminases (AST and ALT)	<input type="checkbox"/>					
*Thyroid Function Tests (TFTs)			<input type="checkbox"/>			<input type="checkbox"/>
*Urinalysis with microscopy	<input type="checkbox"/>					
TB screening (refer to page 34 for more details)						

Yearly cervical human papilloma virus (HPV)
screening - female only



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Monitoring after 2nd/additional treatment course

YEAR 4

Continue monitoring for at least 48 months after last infusion

	Month 37	Month 38	Month 39	Month 40	Month 41	Month 42
Month						
Appointment	Date					
	Time					
	Place					
Nurse/phlebotomist/neurologist initials						
*Full blood count (FBC) with differential	<input type="checkbox"/>					
*Serum creatinine	<input type="checkbox"/>					
*Serum transaminases (AST and ALT)	<input type="checkbox"/>					
*Thyroid Function Tests (TFTs)			<input type="checkbox"/>			<input type="checkbox"/>
*Urinalysis with microscopy	<input type="checkbox"/>					
TB screening (refer to page 34 for more details)						

Notes:

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Monitoring after 2nd/additional treatment course

YEAR 4

Continue monitoring for at least 48 months after last infusion

	Month 43	Month 44	Month 45	Month 46	Month 47	Month 48
Month						
Appointment	Date					
Tip: Set up electronic reminders of your appointment dates	Time					
	Place					
Nurse/phlebotomist/neurologist initials						
*Full blood count (FBC) with differential	<input type="checkbox"/>					
*Serum creatinine	<input type="checkbox"/>					
*Serum transaminases (AST and ALT)	<input type="checkbox"/>					
*Thyroid Function Tests (TFTs)			<input type="checkbox"/>			<input type="checkbox"/>
*Urinalysis with microscopy	<input type="checkbox"/>					
TB screening (refer to page 34 for more details)						

Yearly cervical human papilloma virus (HPV)
screening - female only



Notes:

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Monitoring after 2nd/additional treatment course

YEAR 5

	Month 49	Month 50	Month 51	Month 52	Month 53	Month 54
Month						
Appointment						
Tip: Set up electronic reminders of your appointment dates	Date	Time	Place			
Nurse/phlebotomist/neurologist initials						
*Full blood count (FBC) with differential	<input type="checkbox"/>					
*Serum creatinine	<input type="checkbox"/>					
*Serum transaminases (AST and ALT)	<input type="checkbox"/>					
*Thyroid Function Tests (TFTs)			<input type="checkbox"/>			<input type="checkbox"/>
*Urinalysis with microscopy	<input type="checkbox"/>					
TB screening (refer to page 34 for more details)						

Notes:

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Continue monitoring for at least 48 months after last infusion

*Further explanation of these terms can be found at the end of this booklet

Monitoring after 2nd/additional treatment course

YEAR 5

If you have received any additional treatment courses since your initial two courses, ensure to continue monitoring beyond this point, for at least 48 months after last infusion.

	Month 55	Month 56	Month 57	Month 58	Month 59	Month 60
Month						
Appointment						
Tip: Set up electronic reminders of your appointment dates	Date	Time	Place			
Nurse/phlebotomist/neurologist initials						
*Full blood count (FBC) with differential	<input type="checkbox"/>					
*Serum creatinine	<input type="checkbox"/>					
*Serum transaminases (AST and ALT)	<input type="checkbox"/>					
*Thyroid Function Tests (TFTs)			<input type="checkbox"/>			<input type="checkbox"/>
*Urinalysis with microscopy	<input type="checkbox"/>					
TB screening (refer to page 34 for more details)						

Yearly cervical human papilloma virus (HPV)
screening - female only



Notes:

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RELAPSE RECORD

Date: _____

What happened:

Reported to: _____

Date: _____

What happened: _____

Reported to: _____

Date: _____

What happened:

Reported to: _____

Date: _____

What happened: _____

Reported to: _____



In the event of a relapse, please contact your treating neurologist/MS team. A relapse should also be reported as an adverse event; please see the back of this monitoring calendar for further details.

Date:

What happened:

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Reported to:

Date:

What happened:

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Reported to:

Date:

What happened:

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Reported to:

Date:

What happened:

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Reported to:



In the event of a relapse, please contact your treating neurologist/MS team. A relapse should also be reported as an adverse event; please see the back of this monitoring calendar for further details.

IMPORTANT INFORMATION

After treatment with LEMTRADA®, you may be at risk of developing side effects. Temporally associated side effects have the potential to occur for many days after LEMTRADA® infusion.

More information on self-checking and monitoring, short-term side effects, such as infusion-related reactions/infections, and delayed-onset side effects, such as autoimmune conditions, can be found in the **Patient Information Leaflet** as well as in the **LEMTRADA® Patient Guide** that came in your patient information pack.

If you experience any side effects, immediately talk to your doctor, pharmacist or nurse. Further you can also report side effects directly via the details found on the back page.

What to look out for?

As mentioned above, people receiving LEMTRADA® are at risk of certain autoimmune conditions, including:



Bleeding
disorders



Kidney
conditions



Thyroid
disorders



Liver
conditions

Bleeding disorders

Immune thrombocytopenic purpura (ITP)

ITP is a bleeding disorder resulting from low blood platelet levels. The images below illustrate some of the common symptoms of ITP:



This is an example of a leg with petechiae. Petechiae are small, scattered, "pin prick" spots under the skin that are red, pink or purple. Petechiae can occur anywhere on the patient's body, not just the legs.



This is an example of easy or excessive bruising. This could occur anywhere on the patient's body.



This is an example of purpura under the tongue. Purpura as result of ITP could occur on any part of the skin or mucous membranes, including anywhere in the mouth (under the tongue, roof of the mouth, inner cheeks, tongue, gums).

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

Thrombotic thrombocytopenic purpura (TTP)

A blood clotting disorder called thrombotic thrombocytopenic purpura (TTP), can occur with LEMTRADA®. Blood clots form in blood vessels and can happen in the entire body. Get medical help right away if you have any of the following symptoms: skin or mouth bruising that may appear as red pinpoint dots, with or without unexplained extreme tiredness, fever, confusion, speech changes, yellowing of the skin or eyes (jaundice), low amount of urine, dark coloured urine. It is advised to seek medical attention urgently as TTP can be fatal.

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. In HLH these cells 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, yellow skin, or skin rash you must call your doctor right away to report the symptoms.

Liver conditions

Autoimmune liver conditions, such as autoimmune hepatitis can develop in patients after receiving LEMTRADA®. You may develop elevated levels of serum transaminases and an inflamed liver. 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. Liver inflammation can be monitored by monthly blood tests, before and during treatment courses with LEMTRADA® and for 48 months after your last infusion. More information can be found in the **Patient Guide** within your **Patient Information Pack**.

Kidney conditions

Autoimmune kidney conditions, such as anti-glomerular basement membrane disease (Goodpasture syndrome), can be a rare, delayed consequence of LEMTRADA®. Left untreated, these can lead to kidney failure. Some symptoms include: blood in the urine (your urine may be red or tea-coloured), or swelling in the legs/feet. These kidney conditions can also lead to lung damage, which can result in coughing up blood. Blood and urine tests will help your doctor to monitor for signs of kidney disease.

Thyroid disorders

Autoimmune disorders of the thyroid gland are a common side effect of LEMTRADA®, disrupting the body's ability to make/control thyroid hormones important for metabolism. This can result in either an overactive thyroid (when the thyroid produces too much hormone) or an underactive thyroid (when the thyroid does not produce enough hormone). More information can be found in the **Patient Guide**.

Infusion-associated reactions

Most infusion reactions are mild, but reactions such as fever, hives, an irregular heart rhythm, low blood pressure, nausea, chest pains and allergic reactions can be more serious.

You will be given medicine before you start your treatment in order to reduce any potential infusion reactions. You'll be monitored during, and for at least 2 hours after your infusion to help you manage any symptoms you experience during this period.



Your neurologist may provide you with a tailored treatment approach more suitable to your circumstances. Should you have any questions regarding your treatment with LEMTRADA®, please contact your neurologist. Not all side effects are included in this calendar. Should your general health worsen or if you experience any untoward effects while you are receiving LEMTRADA®, please consult your neurologist/MS team.

Infections

People treated with LEMTRADA® are at increased risk of infection. Typically, infections tend to be mild or moderate and can be treated with standard protocols.

Patients treated with LEMTRADA® are also at a higher risk of developing listeria infection (a bacterial infection caused by ingestion of contaminated foods). Listeria infection can cause serious illness, including meningitis, but can be treated with appropriate medication. To reduce this risk, you should avoid eating uncooked or undercooked meats, soft cheeses and unpasteurised dairy products two weeks before treatment, during the treatment and for at least one month after LEMTRADA® treatment.

Tuberculosis

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.

If you display symptoms of tuberculosis (e.g. shortness of breath, cough, wheezing, chest pain or tightness, night sweats, and coughing up blood) or you have been in contact with someone who has tuberculosis, please contact your doctor to arrange a screening.

GLOSSARY

Full blood count / Complete blood count

Full blood count also referred to as complete blood count is a blood test used to detect a wide range of disorders. It measures various components of the blood, including red blood cells, white blood cells and platelets.

Thyroid function tests

Thyroid function tests are currently the most accurate way to diagnose and monitor thyroid disorders. To make a diagnosis and decide on a treatment course, blood test results are interpreted together with imaging, signs and symptoms as well as general wellbeing.

Serum creatinine

This is a blood test that measures the level of creatinine in your blood. Creatinine is a waste product that forms when creatine breaks down. The level of creatinine in your blood can provide your doctor with information on how well your kidneys are working.

Urinalysis with microscopy

This type of urine test is carried out by examining urine under a microscope. This test is often used to confirm the findings of other tests or to add information to a diagnosis.

Serum transaminases

This is a blood test that tests liver functioning. The level of transaminases (ALT and AST) in your blood can provide your doctor with information on how well your liver is working.

Reporting side effects:

If you experience any side effects, immediately talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the Patient Information Leaflet.

You can also report side effects directly to the Pharmacovigilance Department of Sanofi:

by emailing: **za.drugsafety@sanofi.com**

or calling: **011 256 3700**

By reporting side effects, you can help provide more information on the safety of LEMTRADA®.

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, Floor 5, Building I, Hertford Office Park, 90 Bekker Road, Midrand, 2196. Tel: 011 256 3700. Reg. No. 1996/10381/07 MAT-ZA-2200214 - 1.0 - 03/2022