



# BE DETERM!NED

TO TAKE AN ACTIVE ROLE IN  
YOUR TREATMENT DECISIONS

ALEX,  
LEMTRADA PATIENT

Please see Important Safety Information on pages 28-31 and full Prescribing Information/Medication Guide, including serious side effects.

  
**LEMTRADA**<sup>®</sup>  
alemtuzumab<sup>12mg</sup>  
iv

# WHAT IS LEMTRADA?



## INDICATION

LEMTRADA is a prescription medicine used to treat relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Since treatment with LEMTRADA can increase your risk of getting certain conditions and diseases, LEMTRADA is generally prescribed for people who have tried 2 or more MS medicines that have not worked well enough. LEMTRADA is not recommended for use in patients with clinically isolated syndrome (CIS). It is not known if LEMTRADA is safe and effective for use in children under 17 years of age.

## SELECTED IMPORTANT SAFETY INFORMATION

LEMTRADA can cause serious side effects including autoimmune problems, infusion reactions, stroke, tears in your arteries that supply blood to your brain (carotid and vertebral arteries), some kinds of cancers, thyroid problems, low blood counts (cytopenias), inflammation of the liver, hemophagocytic lymphohistiocytosis, Adult Onset Still's Disease, thrombotic thrombocytopenic purpura, autoimmune encephalitis, bleeding disorder (acquired hemophilia A), serious infections, progressive multifocal leukoencephalopathy (PML), inflammation of the gallbladder without gallstones (acalculous cholecystitis), and swelling of lung tissue (pneumonitis). Because of the risks of autoimmune problems, infusion reactions and some kinds of cancers, LEMTRADA is only available through a restricted program called the Risk Evaluation and Mitigation Strategy (REMS) Program.

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# ABOUT LEMTRADA



“

THE WAY I CAN FEEL  
MORE IN CONTROL IS TO

**LEARN  
ABOUT MY  
OPTIONS.**

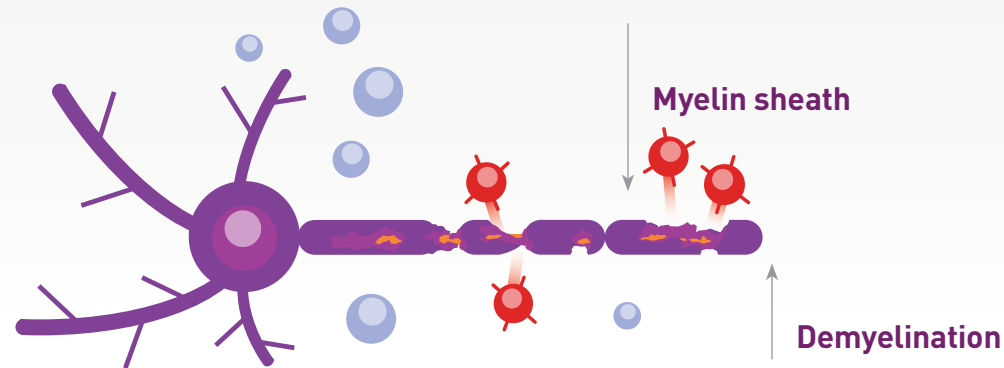
PAUL,  
LEMTRADA PATIENT

”

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# HOW MS IS THOUGHT TO OCCUR



The immune system is made up of many cells—including T and B cells. Immune cells are supposed to help us by attacking threats like bacteria or viruses.

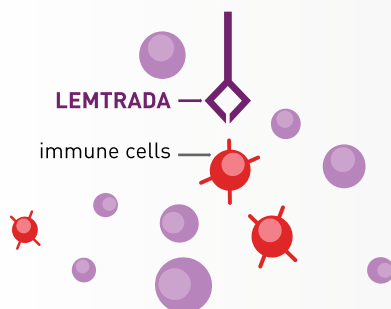
It is believed that overactive T and B immune cells become overly aggressive and are stimulated to mistakenly attack and destroy the myelin sheath, a fatty coating that surrounds and protects nerves in the brain and spinal cord, similar to insulation on a wire. This results in demyelination.

Inflammation in the brain can cause central nervous system lesions, which can show up on magnetic resonance images, or MRIs, of the brain. These lesions can disrupt nerve signals to and from the brain.

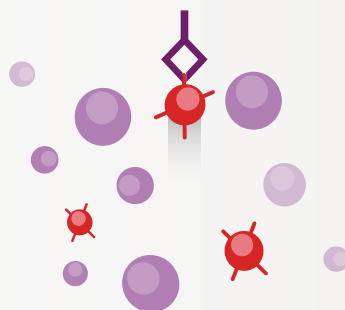
## LEMTRADA IN THE BODY

MS is thought to occur when overactive immune cells attack healthy parts of the central nervous system. It is not known exactly how LEMTRADA works in MS. It is believed to work by targeting many of these cells that may cause relapsing forms of MS.

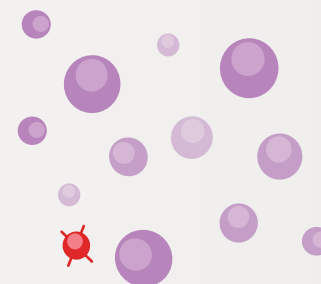
LEMTRADA **recognizes** certain immune cells, including T and B cells.



LEMTRADA **removes** many of those cells.



The immune system slowly **replaces** the cells that were removed with new cells. For some people, certain T cells remained below normal levels when they were measured 1 year after LEMTRADA treatment.



### SELECTED IMPORTANT SAFETY INFORMATION

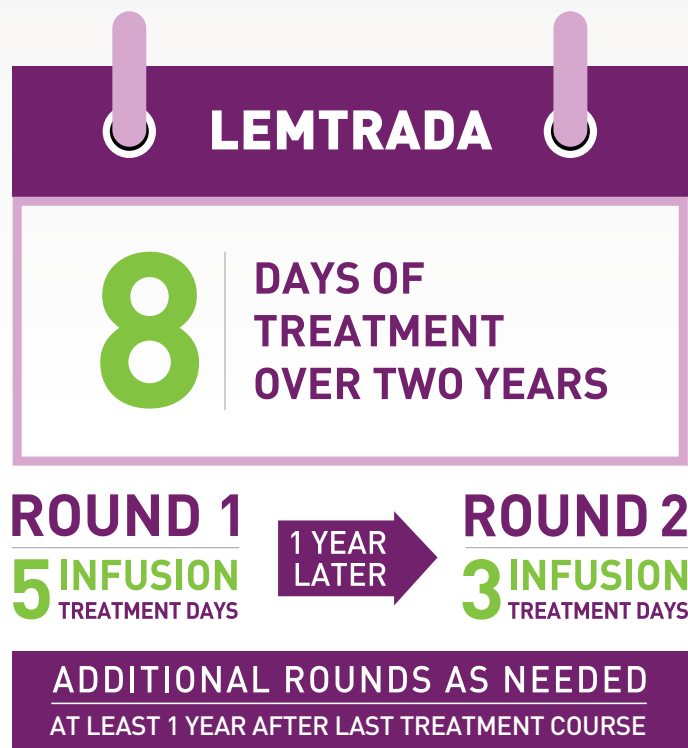
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## HOW LEMTRADA IS GIVEN

LEMTRADA is given by intravenous (IV) infusion through a needle placed in your vein. When starting LEMTRADA, you will have 8 days of infusion, spread over two rounds of treatment that are about 12 months apart. The first round is one infusion a day for 5 days in a row, followed 1 year later by the second round, which is one infusion a day for 3 days in row.



### MONTHLY MONITORING

Monthly monitoring to detect potential serious side effects, including autoimmune side effects and some kinds of cancers, including skin cancer (melanoma), starts after your first infusion and continues until 4 years or longer after the last round of treatment. It is important to have your blood and urine tested, even if you are feeling well and do not have any symptoms from LEMTRADA or your MS. This may help your healthcare provider find potential side effects early.

Additional rounds would occur at least 1 year after your last LEMTRADA treatment and consist of 3 treatment days in a row.

### SELECTED IMPORTANT SAFETY INFORMATION

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# WHAT HAPPENS DURING AN INFUSION



LEMTRADA can cause serious side effects during infusion or up to 24 hours or longer after you receive LEMTRADA. Tell your healthcare provider immediately if you experience any discomfort during or after your infusion.



Before your LEMTRADA infusion begins, you will be given certain medications to help reduce the chance of having a serious infusion reaction or to treat them if they happen.



It will take approximately 4 hours to receive 1 dose of LEMTRADA. The time may vary depending on a number of factors. You will be monitored closely during the infusion and for at least 2 hours following the completion of the infusion to watch for any infusion reactions. You can expect to be at the infusion facility for 8 hours or more per day.

**QUDUS,**  
LEMTRADA  
PATIENT

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# HOW DO I KNOW IF LEMTRADA MAY BE RIGHT FOR ME?

There are a variety of factors that could make a patient appropriate for LEMTRADA treatment. Below are examples of real-life LEMTRADA patients and some of the characteristics of their relapsing MS experiences which may make them appropriate for LEMTRADA treatment.



**KIM, 44**

African American  
Incomplete recovery  
from relapses



**LUIS, 38**

Male  
2 prior treatments



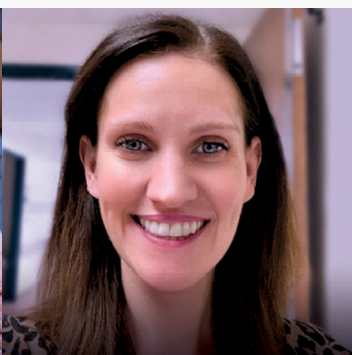
**GINNY, 38**

>3 prior treatments  
Incomplete recovery  
from relapses



**CHARLES, 23**

Male  
African American



**ASHLEY, 38**

Worsening disability  
progression  
>3 prior treatments



**DONNIE, 49**

Male  
Worsening disability  
progression

## SELECTED IMPORTANT SAFETY INFORMATION

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# LEMTRADA CLINICAL TRIALS

“

UNDERSTANDING THE  
**STUDY  
RESULTS**

HELPED ME WITH  
MY DECISION.

**ASHLEY,**  
LEMTRADA PATIENT

”

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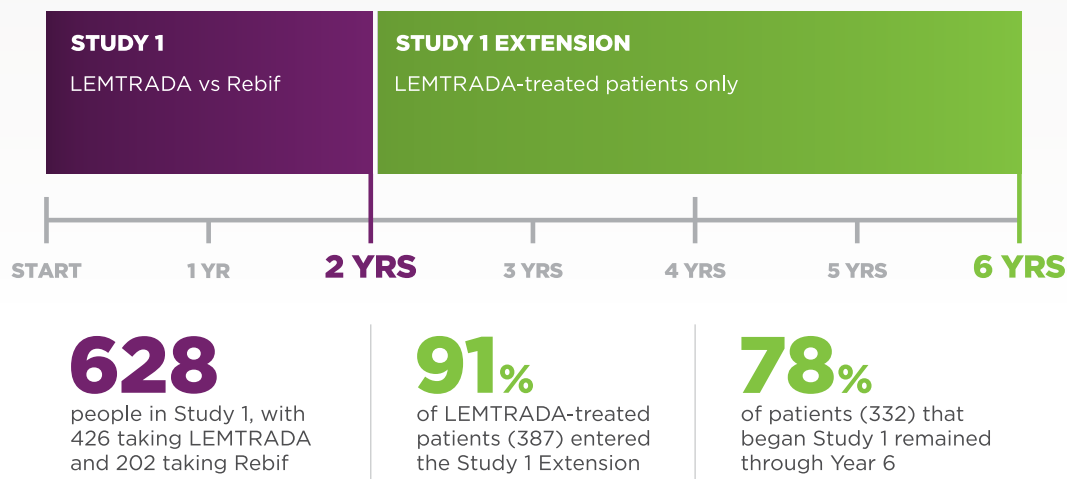
  
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## HOW LEMTRADA WAS STUDIED

LEMTRADA was studied in two 2-year clinical trials against Rebif® (interferon beta-1a) 44 mcg, an interferon that is commonly prescribed for relapsing MS. By comparing against Rebif, and not a placebo, researchers were able to test the efficacy and safety of LEMTRADA against a medication that had already been proven effective.

Patients entering Study 1 had Expanded Disability Status Scale (EDSS) scores of 5 or less and had to have experienced at least 2 relapses during the 2 years prior to the trial and at least 1 relapse while on interferon beta or glatiramer acetate therapy during the year prior to the trial.

Many of the LEMTRADA-treated patients from Study 1 agreed to stay in an Extension Study for an additional 4 years, for a total of 6 years in the studies.



### SELECTED IMPORTANT SAFETY INFORMATION

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# WHO ENTERED THE STUDY 1 CLINICAL TRIAL?



## LEMTRADA PATIENT CHARACTERISTICS AT ENTRY

**AVG. AGE** 35

**GENDER** 66% F / 34% M

**AVG. YEARS WITH MS** 4.5

**AVG. RELAPSES IN PRIOR YEAR** 1.7

**AVG. EDSS** 2.7

**All had relapsed while on a prior MS therapy**

EDSS measures disability progression in people with MS on a scale of 0 to 10, where 0 represents no disability.

## SELECTED IMPORTANT SAFETY INFORMATION

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# HALF OF LEMTRADA-TREATED PATIENTS HAD JUST 2 ROUNDS OF TREATMENT OVER THE 6 YEARS

When starting LEMTRADA, you will have 8 days of infusion, spread over two rounds of treatment that are about 12 months apart. Your healthcare provider could decide that you need additional rounds of treatment. If so, each round would occur at least 1 year after the last treatment and consist of 3 treatment days in a row.

## OF THE 387 PEOPLE WHO ENTERED THE STUDY 1 EXTENSION OF LEMTRADA:

# 50%

**(192) did not receive additional rounds of LEMTRADA**

or any other disease-modifying therapy (DMT).

**29%** (114) received 1 additional round of LEMTRADA

**13%** (50) received 2 additional rounds of LEMTRADA

**2%** (9) received 3 additional rounds of LEMTRADA

**1%** (4) received 4 additional rounds of LEMTRADA

**5%** (18) received another DMT and no additional LEMTRADA rounds

Information beyond 3 treatment courses is limited.

## SELECTED IMPORTANT SAFETY INFORMATION

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# WHAT THE CLINICAL TRIALS TOLD US ABOUT LEMTRADA

## TYPES OF INFORMATION COLLECTED

### PRIMARY

Information that the study set out to do, learn, or prove based on the expected effects of the drug.

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### SECONDARY

Information that adds support and understanding to primary information.

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### TERTIARY

Tertiary or exploratory information may provide additional learnings about clinically important events that may be more closely examined in later studies.

- No definitive conclusions about treatment effects with LEMTRADA can be drawn from tertiary information



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# IS IT POSSIBLE FOR LEMTRADA TO REDUCE RELAPSES?

AT YEAR 2: PRIMARY INFORMATION

PEOPLE WHO TOOK LEMTRADA HAD

**HALF**

AS MANY RELAPSES AS PEOPLE WHO TOOK REBIF

The rate of relapses per year for people who took LEMTRADA was 0.26 vs 0.52 for people who took Rebif.

## SELECTED IMPORTANT SAFETY INFORMATION

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## AT YEAR 2: SECONDARY INFORMATION



**65% OF PEOPLE WHO TOOK LEMTRADA WERE RELAPSE-FREE**

VS 47% OF PEOPLE WHO TOOK REBIF

## YEARS 3-6

**THE ANNUAL PERCENTAGE OF PEOPLE IN THE EXTENSION STUDY WHO TOOK LEMTRADA FREE FROM RELAPSE IN YEARS 3-6 RANGED FROM 79% TO 87%**

## SELECTED IMPORTANT SAFETY INFORMATION

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# WHAT IS CONFIRMED DISABILITY PROGRESSION IN THE LEMTRADA CLINICAL TRIALS?



Confirmed disability progression was defined as at least a 1-point increase (1.5 for patients starting at 0) on the Expanded Disability Status Scale (EDSS) that last for 6 months.

## SELECTED IMPORTANT SAFETY INFORMATION

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“

I'VE MADE IT MY GOAL TO

## **SLOW MY DISABILITY PROGRESSION**

AS MUCH AS POSSIBLE.

**JUSTIN,**  
LEMTRADA PATIENT

”

### **SELECTED IMPORTANT SAFETY INFORMATION**

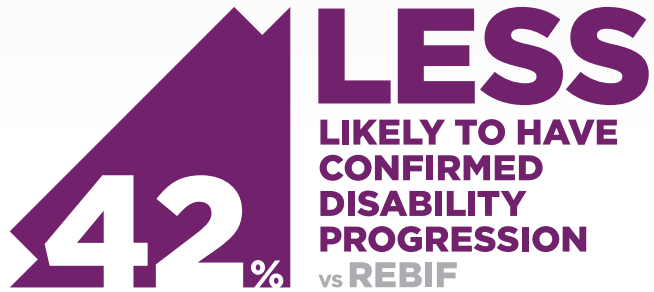
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# IS IT POSSIBLE FOR LEMTRADA TO SLOW DISABILITY PROGRESSION?

## AT YEAR 2: PRIMARY INFORMATION



13% of people who took LEMTRADA experienced confirmed disability progression compared with 21% of those who took Rebif.

A separate study in patients who had no previous MS treatment showed no statistically significant difference in confirmed disability progression between LEMTRADA and Rebif.

## SELECTED IMPORTANT SAFETY INFORMATION

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## AT YEAR 2, 13% OF PEOPLE WHO TOOK LEMTRADA IN STUDY 1 HAD CONFIRMED DISABILITY PROGRESSION. THIS MEANS THAT:

### AT YEAR 2: SECONDARY INFORMATION

**87%** OF PEOPLE WHO TOOK LEMTRADA HAD NO CONFIRMED DISABILITY PROGRESSION VS 79% OF PEOPLE WHO TOOK REBIF

### AT YEAR 6

**72%** OF PEOPLE WHO ENTERED THE EXTENSION STUDY WHO TOOK LEMTRADA HAD NO CONFIRMED DISABILITY PROGRESSION

### SELECTED IMPORTANT SAFETY INFORMATION

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## ADDITIONAL TERTIARY INFORMATION

THESE RESULTS WERE NOT TESTED FOR STATISTICAL SIGNIFICANCE. NO DEFINITIVE CONCLUSIONS ABOUT TREATMENT EFFECTS OF LEMTRADA OR REBIF CAN BE DRAWN FROM THESE TERTIARY DATA FROM THE LEMTRADA CLINICAL TRIALS.

At YEAR 2, 85% of patients who took LEMTRADA had stabilized or improved disability vs 75% of patients who took Rebif.

|  | LEMTRADA |                              | Rebif |
|--|----------|------------------------------|-------|
|  | 28.8%    | <b>Improved Disability</b>   | 16.0% |
|  | 55.9%    | <b>Stabilized Disability</b> | 58.9% |
|  | 15.3%    | <b>Worsened Disability</b>   | 25.1% |

At YEAR 6, 77% of patients who took LEMTRADA had stabilized or improved disability.

|  | LEMTRADA |                              |
|--|----------|------------------------------|
|  | 23.6%    | <b>Improved Disability</b>   |
|  | 53.7%    | <b>Stabilized Disability</b> |
|  | 22.7%    | <b>Worsened Disability</b>   |

### IMPROVED DISABILITY

1-point or greater decrease in EDSS score

### STABILIZED DISABILITY

+ or - half-point or less change in EDSS score

### WORSENE DISABILITY

1-point or greater increase in EDSS score

EDSS measures disability progression in people with MS on a scale of 0 to 10, where 0 represents no disability.



**MORE INFORMATION ON THE LEMTRADA CLINICAL TRIALS CAN BE FOUND HERE**

### SELECTED IMPORTANT SAFETY INFORMATION

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# LEMTRADA SAFETY

“  
MY HEALTHCARE TEAM  
HELPED ME UNDERSTAND  
THE SAFETY. NOW I KNOW  
**WHAT TO  
LOOK FOR.**  
”

LUIS,  
LEMTRADA PATIENT

Please see Important Safety Information on pages 28-31 and full Prescribing Information/Medication Guide, including serious side effects.

LEMTRADA<sup>®</sup>  
alemtuzumab<sup>12mg</sup><sub>iv</sub>

# THE LEMTRADA REMS

Because of the risks of autoimmunity, infusion reactions, and some kinds of cancers, LEMTRADA is only available through a restricted program called the LEMTRADA Risk Evaluation and Mitigation Strategy (REMS) Program.

A REMS program is required by the FDA for certain medications to help ensure that the potential benefits of a drug outweigh its potential risks.

## WHAT DOES THE LEMTRADA REMS DO?



Confirms patients are enrolled and educated about treatment and ongoing monitoring requirements.



Trains and certifies healthcare providers to prescribe LEMTRADA.



Verifies healthcare facilities are enrolled in the program and have on-site access to equipment and personnel trained to manage infusion reactions.



Makes sure approved pharmacies are certified with the program and working with trained facilities.

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**A REMS PROGRAM FOCUSES ON PATIENT SAFETY  
THROUGH EDUCATION AND SUPPORT**

---

**RACHEL & JILL,**  
LEMTRADA PATIENTS



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# POTENTIAL SERIOUS INFUSION REACTIONS

## WHAT THEY ARE

LEMTRADA® (alemtuzumab) can cause serious infusion reactions that can cause death. Serious infusion reactions may happen while you receive, or up to 24 hours or longer after you receive LEMTRADA.

You will receive your infusion at a healthcare facility with equipment and staff trained to manage infusion reactions, including serious allergic reactions, and urgent heart or breathing problems.

You will be watched while you receive, and for 2 hours or longer after you receive, LEMTRADA. If a serious infusion reaction happens while you are receiving LEMTRADA, your infusion may be stopped.

## WHO EXPERIENCED THIS?

**92%** of patients experienced infusion reactions in the LEMTRADA clinical trials

**3%** of these reactions were serious

## SYMPTOMS TO WATCH FOR

Tell your healthcare provider right away if you have any of the following symptoms of a serious infusion reaction during the infusion, and after you have left the healthcare facility:

- swelling in your mouth or throat
- weakness
- chest pain
- trouble breathing
- fast, slow, or irregular heartbeat
- rash

## STROKE AND TEARS IN YOUR ARTERIES THAT SUPPLY BLOOD TO YOUR BRAIN

Some people have had serious and sometimes deadly strokes and tears in their carotid or vertebral arteries within 3 days of receiving LEMTRADA.

Please see Important Safety Information on pages 28-31 and full [Prescribing Information/Medication Guide](#), including serious side effects.

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## PREMEDICATIONS

### Corticosteroids

To lower your chances of getting a serious infusion reaction, your healthcare provider will give you a medicine called corticosteroids before your first 3 infusions of a treatment course.

### Antihistamines and fever reducers

You may also be given antihistamines and/or a fever reducer prior to your infusion to reduce the chances of infusion reactions, or to treat them if they happen.

## OTHER MEDICATIONS

### Antivirals

You'll be given an antiviral starting on your first day of LEMTRADA treatment and you will continue taking it under your healthcare provider's guidance.

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# OTHER SELECTED SIDE EFFECTS AND MONITORING

Some of the serious side effects of LEMTRADA may include autoimmune diseases, which may cause death. These may include blood, thyroid, liver, and kidney disorders (ie, anti-glomerular basement membrane disease). Kidney disease can lead to kidney failure needing dialysis or transplant and can be life-threatening if untreated. LEMTRADA may increase your chance of getting some kinds of cancers, including skin cancer (melanoma), thyroid cancer, and blood cancers (ie, lymphoproliferative disorders and lymphoma).

## MONITORING IS JUST AS IMPORTANT AS GETTING TREATMENT

Certain side effects of LEMTRADA can happen months and even years after treatment. That's why it is important to begin monitoring after your first infusion and continue regular monitoring until 4 years or longer after your last round of treatment. Monitoring can help your healthcare provider find potential side effects early.

### MONITORING INCLUDES:



Monthly blood and urine lab tests.



Ongoing symptom self-checks.



Yearly skin exams are recommended.

It's very important to have your blood and urine tested even if you're feeling well and do not have any symptoms from LEMTRADA or relapsing MS.

Please see Important Safety Information on pages 28-31 and full [Prescribing Information/Medication Guide](#), including serious side effects.

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## YOUR LAB MONITORING OPTIONS



**LAB:** Testing at any LabCorp® or Quest Diagnostics® patient service centers\*



**HEALTHCARE PROVIDER'S OFFICE:** Samples can be taken at your healthcare provider's office. With this option, you may incur a co-pay for your doctor's office visit. However, the cost of analyzing the samples will be covered by the LEMTRADA Central Lab Program.

\*Trademarks not owned by Sanofi corporation are the property of their respective owners.



**HEAR REAL LEMTRADA  
PATIENTS DISCUSS THEIR  
EXPERIENCES POST-INFUSION**

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# IMPORTANT SAFETY INFORMATION

## LEMTRADA can cause serious side effects including:

**Serious autoimmune problems:** Some people receiving LEMTRADA develop a condition where the immune cells in your body attack other cells or organs in the body (autoimmunity), which can be serious and may cause death. Serious autoimmune problems may include:

- Immune thrombocytopenic purpura (ITP), a condition of reduced platelet counts in your blood that can cause severe bleeding that may cause life-threatening problems. Call your healthcare provider (HCP) right away if you have any of the following symptoms: easy bruising, bleeding from a cut that is hard to stop, coughing up blood, heavier menstrual periods than normal, bleeding from your gums or nose that is new or takes longer than usual to stop, small, scattered spots on your skin that are red, pink, or purple.
- Kidney problems called anti-glomerular basement membrane disease, which, if not treated, can lead to severe kidney damage, kidney failure that needs dialysis, a kidney transplant, or death. Call your HCP right away if you have any of the following symptoms: swelling of your legs or feet, blood in the urine (red or tea-colored urine), decrease in urine, fatigue, coughing up blood.

It is important for you to have blood and urine tests before you receive, while you are receiving and every month for 4 years or longer, after you receive your last LEMTRADA infusion.

**Serious infusion reactions:** LEMTRADA can cause serious infusion reactions that may cause death. Serious infusion reactions may happen while you receive, or up to 24 hours or longer after you receive LEMTRADA.

- You will receive your infusion at a healthcare facility with equipment and staff trained to manage infusion reactions, including serious allergic reactions, and urgent heart or breathing problems. You will be watched while you receive, and for 2 hours or longer after you receive, LEMTRADA. If a serious infusion reaction happens while you are receiving LEMTRADA, your infusion may be stopped.

Tell your HCP right away if you have any of the following symptoms of a serious infusion reaction during the infusion, and after you have left the healthcare facility:

- swelling in your mouth or throat
- weakness
- chest pain
- trouble breathing
- fast, slow, or irregular heartbeat
- rash

To lower your chances of getting a serious infusion reaction, your HCP will give you a medicine called corticosteroids before your first 3 infusions of a treatment course. You may also be given other medicines before or after the infusion to try to reduce your chances of having these reactions or to treat them if they happen.

**Stroke and tears in your arteries that supply blood to your brain (carotid and vertebral arteries):** Some people have had serious and sometimes deadly strokes and tears in their carotid or vertebral arteries within 3 days of receiving LEMTRADA. Get help right away if you have any of the following symptoms that may be signs of a stroke or tears in your carotid or vertebral arteries: drooping of parts of your face, weakness on one side, sudden severe headache, difficulty with speech, neck pain.

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## IMPORTANT SAFETY INFORMATION (CONTINUED)

**Certain cancers:** Receiving LEMTRADA may increase your chance of getting some kinds of cancers, including thyroid cancer, skin cancer (melanoma), and blood cancers called lymphoproliferative disorders and lymphoma. Call your HCP if you have the following symptoms that may be a sign of thyroid cancer: new lump, swelling in your neck, pain in front of neck, trouble swallowing or breathing, hoarseness or other voice changes that do not go away, cough that is not caused by a cold.

Have your skin checked before you start receiving LEMTRADA and each year while you are receiving treatment to monitor for symptoms of skin cancer.

**Because of risks of autoimmunity, infusion reactions, and some kinds of cancers, LEMTRADA is only available through a restricted program called the LEMTRADA Risk Evaluation and Mitigation Strategy (REMS) Program.**

**Do not receive LEMTRADA if you:**

- are allergic to alemtuzumab or to any of the inactive ingredients in LEMTRADA
- are infected with human immunodeficiency virus (HIV)
- have an active infection

**Thyroid problems:** Some patients taking LEMTRADA may get an overactive thyroid (hyperthyroidism) or an underactive thyroid (hypothyroidism). Call your HCP if you have: excessive sweating, unexplained weight loss, unexplained weight gain, fast heartbeat, eye swelling, nervousness, feeling cold, worsening tiredness, constipation.

**Low blood counts (cytopenias):** LEMTRADA may cause a decrease in some types of blood cells. Some people with these low blood counts have increased infections. Call your doctor right away if you have symptoms of cytopenias such as: weakness, chest pain, yellowing of the skin or whites of the eyes (jaundice), dark urine, fast heartbeat.

**Inflammation of the liver:** Call your HCP right away if you have symptoms such as unexplained nausea, stomach pain, tiredness, loss of appetite, yellowing of skin or whites of eyes, or bleeding or bruising more easily than normal.

**Hemophagocytic lymphohistiocytosis:** LEMTRADA may increase the risk of overactivity of the immune system that can be fatal if not diagnosed and treated early. If you experience symptoms such as fever, swollen glands, or skin rash, contact your HCP right away.

**Adult Onset Still's Disease (AOSD):** LEMTRADA may cause AOSD, a rare condition that can cause a high fever 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 HCP immediately.

**Thrombotic thrombocytopenic purpura (TTP):** LEMTRADA may cause blood clotting problems that can be fatal. Call your HCP right away if you experience symptoms such as: purplish spots on skin or in mouth due to bleeding under skin, yellowing of skin or whites of eyes (jaundice), feel tired or weak, very pale skin, fever, fast heart rate or short of breath, headache, speech changes, confusion, vision changes, seizure, low amount of urine or dark or bloody urine, stomach pain, nausea, vomiting, or diarrhea.

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## IMPORTANT SAFETY INFORMATION (CONTINUED)

**Autoimmune encephalitis (AIE):** LEMTRADA may cause AIE, a brain disorder which may include symptoms that seem like an MS relapse. Call your HCP right away if you have any of the following symptoms: personality changes, mood changes, seeing things that are not there (hallucinations), agitation, short term memory loss, confusion, movement disorders, or seizures.

**Bleeding disorder (acquired hemophilia A):** LEMTRADA may cause acquired hemophilia A. Call your HCP right away if you have any of the following symptoms: bruising, nose bleeds, bleeding from a cut that may take longer than usual to stop, painful or swollen joints, blood in urine, dark or bloody stools.

**Serious infections:** LEMTRADA may cause you to have a serious infection while you receive and after receiving a course of treatment. Serious infections may include:

- **listeria.** People who receive LEMTRADA have an increased chance of getting a bacterial infection called listeria, which can lead to significant complications or death. Avoid foods that may be a source of listeria or make sure foods are heated well.
- **herpes viral infections.** Some people taking LEMTRADA have an increased chance of getting herpes viral infections. Take medicines as prescribed by your HCP to reduce your chances of getting these infections.
- **tuberculosis.** Your HCP should check you for tuberculosis before you receive LEMTRADA.
- **hepatitis.** People who are at high risk of, or are carriers of, hepatitis B (HBV) or hepatitis C (HCV) may be at risk of irreversible liver damage.

These are not all the possible infections that could happen while on LEMTRADA. Call your HCP right away if you have symptoms of a serious infection such as fever or swollen glands. Talk to your HCP before you get vaccinations after receiving LEMTRADA. Certain vaccinations may increase your chances of getting infections.

**Progressive multifocal leukoencephalopathy (PML):** A rare brain infection that usually leads to death or severe disability has been reported with LEMTRADA. Symptoms of PML get worse over days to weeks. It is important that you call your doctor right away if you have any new or worsening medical problems that have lasted several days, including problems with thinking, eyesight, strength, balance, weakness on one side of your body, using your arms or legs.

**Inflammation of the gallbladder without gallstones (acalculous cholecystitis):** LEMTRADA may increase your chance of getting inflammation of the gallbladder without gallstones, a serious medical condition that can be life-threatening. Call your HCP right away if you have stomach pain or discomfort, fever, nausea, or are vomiting.

**Swelling of lung tissue (pneumonitis):** Some people have had swelling of the lung tissue while receiving LEMTRADA. Call your HCP right away if you have shortness of breath, cough, wheezing, chest pain or tightness, or are coughing up blood.

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## IMPORTANT SAFETY INFORMATION (CONTINUED)

### Before receiving LEMTRADA, tell your HCP if you:

- have bleeding, thyroid, or kidney problems
- have a recent history of infection
- are taking a medicine called Campath® (alemtuzumab)
- have received a live vaccine in the past 6 weeks before receiving LEMTRADA or plan to receive any live vaccines. Ask your HCP if you are not sure if your vaccine is a live vaccine.
- are pregnant or plan to become pregnant. LEMTRADA may harm your unborn baby. You should use birth control while receiving LEMTRADA and for 4 months after your course of treatment.
- are breastfeeding or plan to breastfeed. You and your HCP should decide if you should receive LEMTRADA or breastfeed.

**Tell your HCP about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. LEMTRADA and other medicines may affect each other, causing side effects. Especially tell your HCP if you take medicines that increase your chance of getting infections, including medicines used to treat cancer or to control your immune system.

### The most common side effects of LEMTRADA include:

- rash
- headache
- thyroid problems
- fever
- swelling of your nose and throat
- nausea
- urinary tract infection
- feeling tired
- trouble sleeping
- upper respiratory infection
- herpes viral infection
- hives
- itching
- fungal infection
- joint pain
- pain in your arms or legs
- back pain
- diarrhea
- sinus infection
- mouth pain or sore throat
- tingling sensation
- dizziness
- stomach pain
- sudden redness in face, neck, or chest
- vomiting

Tell your HCP if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of LEMTRADA.

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 iv



# LEMTRADA SUPPORT

“

IT'S REASSURING TO  
KNOW THERE'S

**SOMEWHERE  
I CAN TURN**

WHEN I NEED ANSWERS.

**MEGAN,**  
LEMTRADA PATIENT

”



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## PERSONAL SUPPORT

Whether you're considering LEMTRADA or getting started on treatment, you and your Care Partners can benefit from information and resources to help make smart decisions. That's why LEMTRADA offers personalized support from *MS One to One*®.

**A DEDICATED CASE MANAGER  
ASSIGNED TO EVERY PATIENT**

### Treatment questions? *MS One to One* can help with:

- Getting started on LEMTRADA
- Preparing for your infusions
- Remembering monthly monitoring
- Providing information for financial support



**CALL 24/7\***  
1-855-676-6326



**MORE INFORMATION CAN ALSO BE FOUND  
ON THE *MS ONE TO ONE* WEBSITE**

\*As a member of *MS One to One*, you'll have access to an on-duty Case Manager 24/7.  
Regular *MS One to One* call center hours are Mon-Fri, 8:30 am-8:00 pm ET.

### SELECTED IMPORTANT SAFETY INFORMATION

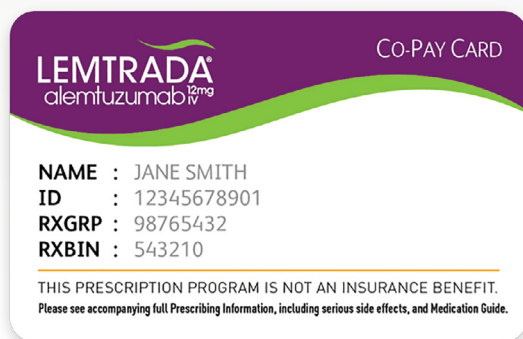
LEMTRADA can cause serious side effects including autoimmune problems, infusion reactions, stroke, tears in your arteries that supply blood to your brain (carotid and vertebral arteries), some kinds of cancers, thyroid problems, low blood counts (cytopenias), inflammation of the liver, hemophagocytic lymphohistiocytosis, Adult Onset Still's Disease, thrombotic thrombocytopenic purpura, autoimmune encephalitis, bleeding disorder (acquired hemophilia A), serious infections, progressive multifocal leukoencephalopathy (PML), inflammation of the gallbladder without gallstones (acalculous cholecystitis), and swelling of lung tissue (pneumonitis). Because of the risks of autoimmune problems, infusion reactions and some kinds of cancers, LEMTRADA is only available through a restricted program called the Risk Evaluation and Mitigation Strategy (REMS) Program.

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# FINANCIAL SUPPORT

To help make treatment costs and co-pays more affordable, we created the LEMTRADA Co-Pay Program. **Through the program, financial assistance is available to help eligible,\* commercially insured patients receive LEMTRADA with:**



**\$0** OUT-OF-POCKET COST  
FOR LEMTRADA

**\$100** PER DAY FOR CHARGES  
RELATED TO THE  
ADMINISTRATION OF  
YOUR LEMTRADA INFUSION  
UP TO

\*Patients who have coverage or prescriptions paid for in part or in full under Medicare, Medicaid, or other state or federally funded healthcare programs are not eligible. The LEMTRADA Co-Pay Program is subject to termination or modification at any time. If you are not eligible for the LEMTRADA Co-Pay Program and need help with out-of-pocket expenses, *MS One to One*® can help review your coverage options. Depending on your specific situation, your *MS One to One* Case Manager can direct you to other patient assistance programs that may offer you financial support. Treatment-related, infusion out-of-pocket costs are not reimbursable in MA, MI, MN, or RI.

## SELECTED IMPORTANT SAFETY INFORMATION

LEMTRADA can cause serious side effects including autoimmune problems, infusion reactions, stroke, tears in your arteries that supply blood to your brain (carotid and vertebral arteries), some kinds of cancers, thyroid problems, low blood counts (cytopenias), inflammation of the liver, hemophagocytic lymphohistiocytosis, Adult Onset Still's Disease, thrombotic thrombocytopenic purpura, autoimmune encephalitis, bleeding disorder (acquired hemophilia A), serious infections, progressive multifocal leukoencephalopathy (PML), inflammation of the gallbladder without gallstones (acalculous cholecystitis), and swelling of lung tissue (pneumonitis). Because of the risks of autoimmune problems, infusion reactions and some kinds of cancers, LEMTRADA is only available through a restricted program called the Risk Evaluation and Mitigation Strategy (REMS) Program.

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# PARTNERING WITH YOUR HEALTHCARE PROVIDER

If you're considering LEMTRADA for your relapsing MS, you'll need to find out if it is the right treatment choice for you. That decision can only be made by partnering closely with your healthcare providers.

It's important to discuss your treatment goals and expectations with your healthcare providers. Let them know what you think about your current relapsing MS treatment. The following pages can help show you how.

## SELECTED IMPORTANT SAFETY INFORMATION

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## DISCUSSION GUIDE

### MAKING THE CONVERSATION COUNT

At an appointment with your healthcare provider, you may not always remember all of the questions you wanted to ask. To help you have a more in-depth conversation with your healthcare team, fill out this Discussion Guide and bring it to your next appointment.

#### QUESTIONS TO ASK YOURSELF

Put a check mark in the appropriate boxes.

#### HOW MANY RELAPSES HAVE I HAD IN THE PAST COUPLE OF YEARS?

- None                       2  
 1                               3 or more

#### IN THE PAST COUPLE OF YEARS, I FEEL MY MS DISABILITY PROGRESSION HAS:

- Worsened  
 Stayed the same  
 Improved

#### HOW DO I FEEL ABOUT MY CURRENT RELAPSING MS TREATMENT?

- Not at all satisfied  
 Somewhat satisfied  
 Satisfied  
 Completely satisfied

### SELECTED IMPORTANT SAFETY INFORMATION

LEMTRADA can cause serious side effects including autoimmune problems, infusion reactions, stroke, tears in your arteries that supply blood to your brain (carotid and vertebral arteries), some kinds of cancers, thyroid problems, low blood counts (cytopenias), inflammation of the liver, hemophagocytic lymphohistiocytosis, Adult Onset Still's Disease, thrombotic thrombocytopenic purpura, autoimmune encephalitis, bleeding disorder (acquired hemophilia A), serious infections, progressive multifocal leukoencephalopathy (PML), inflammation of the gallbladder without gallstones (acalculous cholecystitis), and swelling of lung tissue (pneumonitis). Because of the risks of autoimmune problems, infusion reactions and some kinds of cancers, LEMTRADA is only available through a restricted program called the Risk Evaluation and Mitigation Strategy (REMS) Program.

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## DISCUSSION GUIDE

Asking questions about your condition and your treatment options can help your healthcare provider understand that you want to be a partner in the decision-making process. Here are some conversation starters.

### KEY QUESTIONS FOR YOUR HEALTHCARE PROVIDER

**How many relapses are too many?**

---

**Are you seeing signs of my disease progressing?**

---

**What should I be able to expect from a relapsing MS treatment?**

---

**What factors do you consider before prescribing LEMTRADA?**

### SELECTED IMPORTANT SAFETY INFORMATION

LEMTRADA can cause serious side effects including autoimmune problems, infusion reactions, stroke, tears in your arteries that supply blood to your brain (carotid and vertebral arteries), some kinds of cancers, thyroid problems, low blood counts (cytopenias), inflammation of the liver, hemophagocytic lymphohistiocytosis, Adult Onset Still's Disease, thrombotic thrombocytopenic purpura, autoimmune encephalitis, bleeding disorder (acquired hemophilia A), serious infections, progressive multifocal leukoencephalopathy (PML), inflammation of the gallbladder without gallstones (acalculous cholecystitis), and swelling of lung tissue (pneumonitis). Because of the risks of autoimmune problems, infusion reactions and some kinds of cancers, LEMTRADA is only available through a restricted program called the Risk Evaluation and Mitigation Strategy (REMS) Program.

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# ARE YOU DETERMINED

TO TAKE THE NEXT STEP  
IN YOUR TREATMENT  
JOURNEY?



Make an appointment with your  
healthcare provider and find  
out if LEMTRADA could be a  
treatment option for you.

FOR MORE INFORMATION  
VISIT [LEMTRADA.COM](http://LEMTRADA.COM)

  
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## INDICATION

LEMTRADA is a prescription medicine used to treat relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Since treatment with LEMTRADA can increase your risk of getting certain conditions and diseases, LEMTRADA is generally prescribed for people who have tried 2 or more MS medicines that have not worked well enough.

LEMTRADA is not recommended for use in patients with clinically isolated syndrome (CIS). It is not known if LEMTRADA is safe and effective for use in children under 17 years of age.

## SELECTED IMPORTANT SAFETY INFORMATION

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