> “Make sure you are knowledgeable about your treatment.”
>
> – Jennifer
> LEMTRADA Patient

# If your current relapsing MS therapy isn’t meeting your expectations, it may be time to consider LEMTRADA as a treatment option.

LEMTRADA (alemtuzumab) is a prescription medicine used to treat adults with relapsing forms of multiple sclerosis (MS). Because of its risks, LEMTRADA is generally used in people who have tried 2 or more MS medicines that have not worked well enough. 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, some kinds of cancers, thyroid problems, low blood counts (cytopenias), serious infections, inflammation of the gallbladder without gallstones (acalculous cholecystitis), and swelling of lung tissue (pneumonitis). Because of these risks, LEMTRADA is only available through a restricted program called the Risk Evaluation and Mitigation Strategy (REMS) Program.

**Please see Important Safety Information on pages 17–19 and enclosed full Prescribing Information / Medication Guide, including serious side effects.**

LEMTRADA® alemtuzumab 12mg IV

# Your determination to challenge relapsing MS knows no boundaries

## CONTENTS



### SELECTED IMPORTANT SAFETY INFORMATION

LEMTRADA can cause serious side effects including autoimmune problems, infusion reactions, some kinds of cancers, thyroid problems, low blood counts (cytopenias), serious infections, inflammation of the gallbladder without gallstones (acalculous cholecystitis), and swelling of lung tissue (pneumonitis). Because of these risks, LEMTRADA is only available through a restricted program called the Risk Evaluation and Mitigation Strategy (REMS) Program.

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# LEMTRADA AT A GLANCE

If you've been considering your treatment options for relapsing MS, it may be time for you and your healthcare provider to discuss LEMTRADA.

### 5 THINGS YOU SHOULD KNOW:

1. LEMTRADA is a prescription infusion medicine used to treat adults with relapsing multiple sclerosis (MS). It's generally used in people who have tried 2 or more MS medicines that haven't worked well enough.

2. LEMTRADA is the first relapsing MS medication that is administered in 8 doses over two years. Before treatment, you'll be given certain medications. You'll be monitored after your first treatment, and monitoring will continue until four years or longer after your last treatment.

3. LEMTRADA was studied vs Rebif® (interferon beta-1a) in a 2-year study. Learn about the results in this brochure.

4. Because of the risks of autoimmunity, infusion reactions, and some kinds of cancers, LEMTRADA is only available through a REMS Program.

5. LEMTRADA offers all patients additional resources and support, including financial assistance for eligible patients, through the *MS One to One*® program.

**"What I had been doing was not making a difference. I decided to talk to my doctor about LEMTRADA."**

**–Catherine**
**LEMTRADA Patient**

**To hear from others who decided with their healthcare providers to choose LEMTRADA, visit lemtrada.com/patientstories**

## SELECTED IMPORTANT SAFETY INFORMATION

LEMTRADA can cause serious side effects including autoimmune problems, infusion reactions, some kinds of cancers, thyroid problems, low blood counts (cytopenias), serious infections, inflammation of the gallbladder without gallstones (acalculous cholecystitis), and swelling of lung tissue (pneumonitis). Because of these risks, LEMTRADA is only available through a restricted program called the Risk Evaluation and Mitigation Strategy (REMS) Program.

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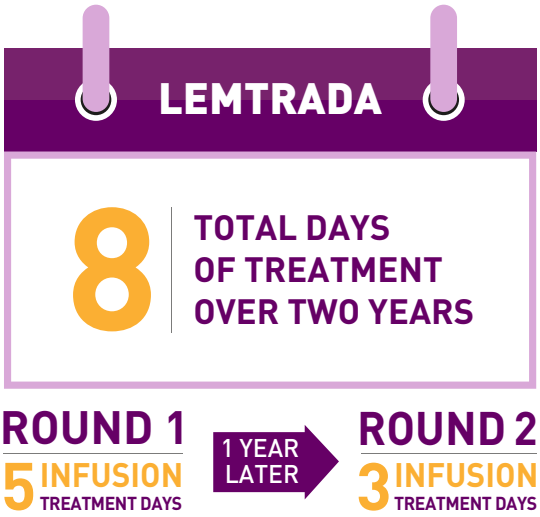
# HOW LEMTRADA IS GIVEN

## LEMTRADA is given by infusion (IV), 5 days in a row. One year later, there is a second round of IV treatments for 3 days in a row.




LEMTRADA is the first relapsing MS medication that is administered in 8 doses over two years. After your first treatment, you'll start monthly monitoring to detect potential side effects. Monthly monitoring will continue until 4 years, or longer, after your last treatment course.

- 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 will be given certain medications prior to treatment
- LEMTRADA can cause serious side effects during infusions 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. You may also be given other medicines before or after the infusion to try to reduce your chances of getting these reactions or to treat them after they happen
- You will also need monthly blood and urine tests, self-checks, and yearly skin checks. These help to monitor for possible side effects that can show up months or even years after your last infusion, including autoimmune side effects and some kinds of cancers, including skin cancer (melanoma). 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. Monitoring may help your healthcare provider find side effects early and will increase your chances of getting better

## SELECTED IMPORTANT SAFETY INFORMATION

LEMTRADA can cause serious side effects including autoimmune problems, infusion reactions, some kinds of cancers, thyroid problems, low blood counts (cytopenias), serious infections, inflammation of the gallbladder without gallstones (acalculous cholecystitis), and swelling of lung tissue (pneumonitis). Because of these risks, LEMTRADA is only available through a restricted program called the Risk Evaluation and Mitigation Strategy (REMS) Program.

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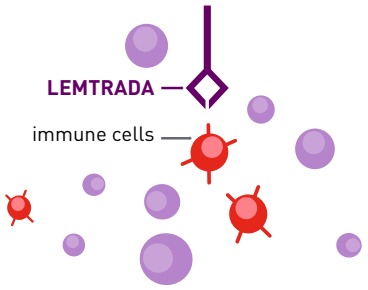
# LEMTRADA IN THE BODY

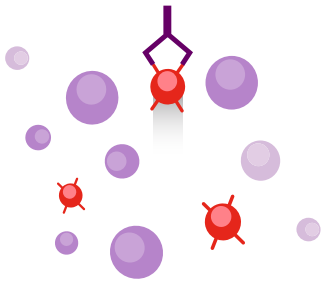
MS is thought to occur when overactive immune cells attack healthy parts of the central nervous system. LEMTRADA is believed to work by targeting many of these cells that may cause relapsing forms of MS. It is not known exactly how LEMTRADA works in MS.

## DURING TREATMENT

**LEMTRADA RECOGNIZES**
certain immune cells in the body, including those thought to cause MS.



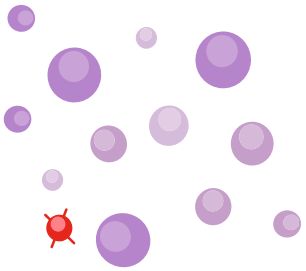

**LEMTRADA REMOVES**
many of those cells.



## AFTER TREATMENT

**YOUR IMMUNE SYSTEM**
slowly begins to replace the cells that were removed with new cells.

**FOR SOME PEOPLE,**
certain cell types remain below normal levels when measured 1 year after treatment.



## SELECTED IMPORTANT SAFETY INFORMATION

LEMTRADA can cause serious side effects including autoimmune problems, infusion reactions, some kinds of cancers, thyroid problems, low blood counts (cytopenias), serious infections, inflammation of the gallbladder without gallstones (acalculous cholecystitis), and swelling of lung tissue (pneumonitis). Because of these risks, LEMTRADA is only available through a restricted program called the Risk Evaluation and Mitigation Strategy (REMS) Program.

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# HOW LEMTRADA WAS STUDIED

LEMTRADA was studied in two 2-year clinical trials against Rebif, a commonly used medication for relapsing MS.

- When LEMTRADA was being studied, researchers decided to measure LEMTRADA's effectiveness against Rebif 44 mcg, a commonly prescribed MS medication. Many other studies use a placebo, which is no drug at all
- This was done in two 2-year clinical trials with a total of 1191 people with relapsing MS that were chosen at random to receive either LEMTRADA or Rebif
- LEMTRADA was studied in both people who had a relapse on an MS therapy and people who had never been on an MS therapy before
- Both studies included people who had experienced at least 2 relapses during the 2 years prior to the trial, and at least 1 relapse during the year prior to the trial
- Participants in Study 1 had to have rated 5.0 or lower on the Expanded Disability Status Scale (EDSS), while participants in Study 2 rated 3.0 or lower. EDSS measures disability progression in people with MS on a scale of 0 to 10, where 0 represents no disability
- In addition, participants in Study 1 had to have relapsed on interferon beta or glatiramer acetate

**Learn more about MS and how LEMTRADA is thought to work in the body.**

**Visit lemtrada.com/inthebody**

## SELECTED IMPORTANT SAFETY INFORMATION

LEMTRADA can cause serious side effects including autoimmune problems, infusion reactions, some kinds of cancers, thyroid problems, low blood counts (cytopenias), serious infections, inflammation of the gallbladder without gallstones (acalculous cholecystitis), and swelling of lung tissue (pneumonitis). Because of these risks, LEMTRADA is only available through a restricted program called the Risk Evaluation and Mitigation Strategy (REMS) Program.

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## INSIDE THE CLINICAL TRIALS

**“My doctor suggested LEMTRADA. I did some research and decided that was the route that I was going to take.”**

**–Stephanie**
**LEMTRADA Patient**

# CLINICAL STUDY RESULTS

LEMTRADA was studied in two 2-year clinical trials against Rebif, a commonly used medication for relapsing MS.

**STUDY 1** **A 2-year clinical trial of people who had a relapse on an MS therapy**

### LEMTRADA: Proven to cut relapses in half over 2 years

**49%**
**FEWER RELAPSES**
**WITH LEMTRADA**
vs REBIF

The people taking LEMTRADA had nearly half as many relapses over 2 years compared to those taking Rebif.

The rate of relapses per year with LEMTRADA was 0.26 vs 0.52 with Rebif.

### LEMTRADA: Proven to help most people live relapse-free at 2 years

**65%**
**RELAPSE-FREE**
**WITH LEMTRADA**
vs REBIF

65% of people taking LEMTRADA were relapse-free at 2 years compared to 47% of people given Rebif.

**STUDY 2** **A 2-year clinical trial of people who had never been on an MS therapy.**
In this study, LEMTRADA was proven to cut relapses in half (55%) vs Rebif. The rate of relapses per year with LEMTRADA was 0.18 vs 0.39 with Rebif.

## SELECTED IMPORTANT SAFETY INFORMATION

LEMTRADA can cause serious side effects including autoimmune problems, infusion reactions, some kinds of cancers, thyroid problems, low blood counts (cytopenias), serious infections, inflammation of the gallbladder without gallstones (acalculous cholecystitis), and swelling of lung tissue (pneumonitis). Because of these risks, LEMTRADA is only available through a restricted program called the Risk Evaluation and Mitigation Strategy (REMS) Program.

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# CLINICAL STUDY RESULTS

LEMTRADA was studied in two 2-year clinical trials against Rebif, a commonly used medication for relapsing MS.

**STUDY 1** **A 2-year clinical trial of people who had a relapse on an MS therapy**

## LEMTRADA: Proven to slow confirmed disability progression in people who relapsed on a prior therapy

**42% LESS CONFIRMED DISABILITY PROGRESSION**

People who had a relapse on an MS therapy and switched to LEMTRADA had 42% less confirmed disability progression* at 2 years compared to people receiving Rebif.

**87% NO CONFIRMED DISABILITY PROGRESSION**

87% of people taking LEMTRADA did not experience confirmed disability progression* at 2 years compared to 79% taking Rebif.

That means 13% of people taking LEMTRADA experienced confirmed disability progression, compared to 21% taking Rebif.

**STUDY 2** **A 2-year clinical trial of people who had never been on an MS therapy.** In this study, those taking LEMTRADA had 30% less confirmed disability progression* compared with those taking Rebif, with 8% of LEMTRADA patients and 11% of Rebif patients experiencing confirmed disability progression at 2 years. The difference was not significant.

*Confirmed disability progression is defined as at least 1-point increase (1.5 for patients starting at 0) on the EDSS that lasts for 6 months.

## SELECTED IMPORTANT SAFETY INFORMATION

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# If you're relapsing on your current MS medication, it may be time to talk to your healthcare provider about LEMTRADA

LEMTRADA was proven effective in a 2-year trial of people who had a relapse on an MS therapy.

- Patients experienced 49% fewer relapses vs Rebif
- 65% of patients were relapse-free at 2 years
- Patients experienced 42% less confirmed disability progression vs Rebif
  - –In a 2-year trial of people who had never been on an MS therapy, confirmed disability progression was not significantly different compared to Rebif.
- LEMTRADA can cause serious side effects including autoimmune problems, infusion reactions, some kinds of cancers, thyroid problems, low blood counts (cytopenias), serious infections, and swelling of lung tissue (pneumonitis).

LEMTRADA (alemtuzumab) is a prescription medicine used to treat adults with relapsing forms of multiple sclerosis (MS). Because of its risks, LEMTRADA is generally used in people who have tried 2 or more MS medicines that have not worked well enough. It is not known if LEMTRADA is safe and effective for use in children under 17 years of age.

"Inform yourself as best you can."

–Jzon
LEMTRADA Patient

## SELECTED IMPORTANT SAFETY INFORMATION

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## SELECTED SIDE EFFECTS

**“Everybody’s relapsing MS and treatment plan are different, and everybody reacts differently to medications.”**

**–Ryan**
**LEMTRADA Patient**

# A LOOK AT POTENTIAL 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. 92% of patients experienced infusion reactions on LEMTRADA and 3% of these reactions were serious.

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
- trouble breathing
- weakness
- fast, slow, or irregular heartbeat
- chest pain
- rash

**You are encouraged to report side effects of prescription drugs to the FDA.**

**Visit www.fda.gov/medwatch or call 1-800-FDA-1088.**

## SELECTED IMPORTANT SAFETY INFORMATION

LEMTRADA can cause serious side effects including autoimmune problems, infusion reactions, some kinds of cancers, thyroid problems, low blood counts (cytopenias), serious infections, inflammation of the gallbladder without gallstones (acalculous cholecystitis), and swelling of lung tissue (pneumonitis). Because of these risks, LEMTRADA is only available through a restricted program called the Risk Evaluation and Mitigation Strategy (REMS) Program.

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# PREMEDICATIONS

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. You may also be given other medicines before or after the infusion to try to reduce your chances of having these reactions or herpes viral infection.

These are the premedications your healthcare provider may offer:

| Corticosteroids | Antihistamines and/or fever reducers | Antivirals |
|---|---|---|
| These will be given to you right before your LEMTRADA infusion for the first 3 days of each round of treatment | Your healthcare provider may consider administering antihistamines and a fever reducer prior to your LEMTRADA infusion | You'll be given an antiviral before treatment and will continue taking it until your immune cells reach certain levels |

Infusion reactions can occur despite pretreatment.

# THE LEMTRADA REMS PROGRAM

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.

During an appointment, your healthcare provider will tell you more about the program and how to enroll.

**"I complete monthly monitoring and it feels good to know someone is checking on me."**

**–Catherine**
**LEMTRADA Patient**

## SELECTED IMPORTANT SAFETY INFORMATION

LEMTRADA can cause serious side effects including autoimmune problems, infusion reactions, some kinds of cancers, thyroid problems, low blood counts (cytopenias), serious infections, inflammation of the gallbladder without gallstones (acalculous cholecystitis), and swelling of lung tissue (pneumonitis). Because of these risks, LEMTRADA is only available through a restricted program called the Risk Evaluation and Mitigation Strategy (REMS) Program.

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# A LOOK AT THE MOST COMMON SIDE EFFECTS

In two 2-year clinical trials, LEMTRADA was studied in over 800 patients.

**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

## SELECTED IMPORTANT SAFETY INFORMATION

LEMTRADA can cause serious side effects including autoimmune problems, infusion reactions, some kinds of cancers, thyroid problems, low blood counts (cytopenias), serious infections, inflammation of the gallbladder without gallstones (acalculous cholecystitis), and swelling of lung tissue (pneumonitis). Because of these risks, LEMTRADA is only available through a restricted program called the Risk Evaluation and Mitigation Strategy (REMS) Program.

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# MONITORING

While LEMTRADA is given in 2 treatment courses over 2 years, regular monitoring is very important because some of the side effects of LEMTRADA can happen months and even years after treatment.

Serious side effects can include autoimmune diseases, which may cause death. These may include blood, thyroid, and kidney disorders (i.e., 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 also be associated with some kinds of cancers, including skin cancer (melanoma), thyroid cancer, and blood cancers (i.e., lymphoproliferative disorders and lymphoma).

Monitoring may help your healthcare provider find side effects early and will increase your chances of getting better. It is important to have your blood and urine tested, even if you are feeling well and do not have symptoms from LEMTRADA or MS.

Monitoring includes:

- monthly blood and urine lab tests
- ongoing symptom self-checks
- yearly skin checks

## YOU HAVE LAB MONITORING OPTIONS

If you choose LEMTRADA, you will have a range of free-of-charge options for monthly blood and urine testing. You can be tested at home, work, or your healthcare provider's office.* Talk to your healthcare provider about which option works best for you.

The following lab monitoring options are covered by the LEMTRADA Central Lab Program at no cost to you:

**Testing at LabCorp or Quest Diagnostics patient service centers**

**Lab tech visits in the comfort of your home or office**

**Testing at your healthcare provider's office***

*If the samples are taken at your healthcare provider's office, you may have to pay a co-pay cost. However, the cost of analyzing the samples will be covered by the LEMTRADA Central Lab Program.

## SELECTED IMPORTANT SAFETY INFORMATION

LEMTRADA can cause serious side effects including autoimmune problems, infusion reactions, some kinds of cancers, thyroid problems, low blood counts (cytopenias), serious infections, inflammation of the gallbladder without gallstones (acalculous cholecystitis), and swelling of lung tissue (pneumonitis). Because of these risks, LEMTRADA is only available through a restricted program called the Risk Evaluation and Mitigation Strategy (REMS) Program.

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"The more you understand about the path you're about to embark upon, the less fear you have."

–Jzon
LEMTRADA Patient

## PERSONAL SUPPORT

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

ms one to one®

**Call an *MS One to One* Nurse now at**

**1-855-676-6326**

**for free support, available**

**24/7***

*As a member of *MS One to One*, you'll have access to an on-duty Nurse 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, some kinds of cancers, thyroid problems, low blood counts (cytopenias), serious infections, inflammation of the gallbladder without gallstones (acalculous cholecystitis), and swelling of lung tissue (pneumonitis). Because of these risks, LEMTRADA is only available through a restricted program called the Risk Evaluation and Mitigation Strategy (REMS) Program.

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Your *MS One to One*® Nurse can answer questions you may have about:

- Getting started on LEMTRADA
- Understanding the benefits and risks of LEMTRADA
- Preparing you for your infusions
- Remembering monthly monitoring
- Finding resources for financial support

Even if your dedicated Nurse is not available, you can speak with one of the *MS One to One* Nurses, on duty 24/7,* by calling 1-855-676-6326.

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

**"My *MS One to One* Nurse? She's been amazing. She keeps up with me and I stay on track with what I need to do."**

**–Ryan**
**LEMTRADA Patient**

## SELECTED IMPORTANT SAFETY INFORMATION

LEMTRADA can cause serious side effects including autoimmune problems, infusion reactions, some kinds of cancers, thyroid problems, low blood counts (cytopenias), serious infections, inflammation of the gallbladder without gallstones (acalculous cholecystitis), and swelling of lung tissue (pneumonitis). Because of these risks, LEMTRADA is only available through a restricted program called the Risk Evaluation and Mitigation Strategy (REMS) Program.

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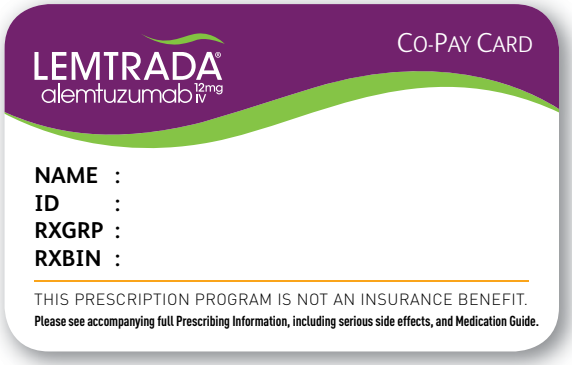
# FINANCIAL SUPPORT FOR LEMTRADA

Take advantage of the LEMTRADA Co-Pay Program.




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

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

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

## Call an *MS One to One*® Nurse now at 1-855-676-6326 for free support 24/7†

*Patients who have coverage or prescriptions paid for in part or in full under Medicare, Medicaid, or other state or federally funded healthcare are not eligible. The LEMTRADA Co-Pay Program is subject to termination or modification at any time. Depending on your specific situation, your *MS One to One* Nurse can direct you to other patient assistance programs that may offer you financial support. Commercially insured residents of Massachusetts, Minnesota, Michigan, and Rhode Island are not eligible for infusion-related financial assistance.

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

## Show your determination

**Ask your healthcare provider about LEMTRADA and attend an event near you. Visit lemtrada.com/events**

## SELECTED IMPORTANT SAFETY INFORMATION

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"Any big decision, you have to consider both the pros and cons."

–Nicole
LEMTRADA Patient

## 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 thrombocytopenia, which is when reduced platelet counts in your blood cause severe bleeding that, if not treated, may cause life-threatening problems. Call your healthcare provider right away if you have any of the following symptoms: easy bruising; bleeding from a cut that is hard to stop; 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 can, if untreated, lead to severe kidney damage, kidney failure that needs dialysis, a kidney transplant, or death. Call your healthcare provider right away if you have any of the following symptoms: blood in the urine (red or tea-colored urine); swelling of legs or feet; 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 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
- trouble breathing
- weakness
- fast, slow, or irregular heartbeat
- chest pain
- rash

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## IMPORTANT SAFETY INFORMATION (continued)

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. 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 after they happen.

**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 healthcare provider 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
- hoarseness or other voice changes that do not go away
- trouble swallowing or breathing
- 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 infected with human immunodeficiency virus (HIV).

**Thyroid problems:** Some patients taking LEMTRADA may get an overactive thyroid (hyperthyroidism) or an underactive thyroid (hypothyroidism). Call your healthcare provider if you have any of these symptoms:

- excessive sweating
- unexplained weight loss
- eye swelling
- nervousness
- fast heartbeat
- unexplained weight gain
- 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

**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:

- **Herpes viral infections.** Some people taking LEMTRADA have an increased chance of getting herpes viral infections. Take any medicines as prescribed by your healthcare provider to reduce your chances of getting these infections.
- **Tuberculosis.** Your healthcare provider 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.
- **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 that may contain listeria are heated well.

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

**Please see Important Safety Information on pages 17–19 and enclosed full Prescribing Information / Medication Guide, including serious side effects.**

LEMTRADA® alemtuzumab 12mg IV

## IMPORTANT SAFETY INFORMATION (continued)

**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 healthcare provider right away if you have any of the following symptoms:

- stomach pain or discomfort
- fever
- nausea or vomiting

**Swelling of lung tissue (pneumonitis):** Some people have had swelling of the lung tissue while receiving LEMTRADA. Call your healthcare provider right away if you have the following symptoms:

- shortness of breath
- cough
- wheezing
- chest pain or tightness
- coughing up blood

**Before receiving LEMTRADA, tell your healthcare provider if you:**

- are taking a medicine called Campath® (alemtuzumab)
- have bleeding, thyroid, or kidney problems
- have HIV
- have a recent history of infection
- have received a live vaccine in the past 6 weeks before receiving LEMTRADA or plan to receive any live vaccines. Ask your healthcare provider 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 healthcare provider should decide if you should receive LEMTRADA or breastfeed. You should not do both.

**Tell your healthcare provider 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 healthcare provider 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 healthcare provider 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.

**Please see Important Safety Information on pages 17–19 and enclosed full Prescribing Information / Medication Guide, including serious side effects.**


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