

MEDICATION GUIDE

LEMTRADA® (lem-TRA-da)
(alemtuzumab)

Injection for intravenous infusion

Rx Only

Read this Medication Guide before you start receiving LEMTRADA and before you begin each treatment course. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

What is the most important information I should know about LEMTRADA?

LEMTRADA can cause serious side effects, including:

1. 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).** LEMTRADA may cause the number of platelets in your blood to be reduced (ITP). ITP can 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.** LEMTRADA may cause a serious kidney problem, called anti-glomerular basement membrane disease. If this happens and you do not get treated, anti-glomerular basement membrane disease can 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 in your legs or feet
- coughing up blood

Side effects may happen while you receive LEMTRADA and for 4 years after you stop receiving LEMTRADA. Your healthcare provider will order blood and urine tests before you receive, while you are receiving, and every month for 4 years after you receive your last LEMTRADA infusion. You may need to continue these blood and urine tests after 4 years if you have any autoimmune signs or symptoms. The blood and urine tests will help your healthcare provider watch for signs and symptoms of serious autoimmune problems.

It is important to have your blood and urine tested, even if you are feeling well and do not have any symptoms from LEMTRADA and your multiple sclerosis. This may help your healthcare provider find any problems early and will increase your chances of getting better.

2. 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. You will be watched while you receive and for 2 hours after you receive LEMTRADA. **It is important** that you stay at the infusion center for **2 hours** after your infusion is finished or longer if your healthcare provider decides you need to stay

longer. 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 heart beat
- chest pain
- rash

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 reduce your chances of these reactions or to treat them after they happen.

3. 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 the front of your neck
- hoarseness or other voice changes that do not go away
- trouble swallowing or breathing
- cough that is not caused by a cold

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

Because of your risk of autoimmunity, infusion reactions and the risk of some kinds of cancers, LEMTRADA is only available through a restricted program called the LEMTRADA Risk Evaluation and Mitigation Strategy (REMS) Program. Call 1-855-676-6326 to enroll in the LEMTRADA REMS Program.

- You and your healthcare provider must be enrolled in the LEMTRADA REMS Program.
- LEMTRADA can only be given at a certified healthcare facility that participates in the LEMTRADA REMS Program. Your healthcare provider can give you information on how to find a certified healthcare facility.
- Read the LEMTRADA REMS “What You Need to Know About LEMTRADA Treatment: A Patient Guide” and “What you Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide” after you are enrolled in the program.
- Carry your LEMTRADA REMS Patient Safety Information Card with you in case of an emergency.

What is LEMTRADA?

LEMTRADA 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.

Who should not receive LEMTRADA?

Do not receive LEMTRADA if you are infected with human immunodeficiency virus (HIV).

What should I tell my healthcare provider before receiving LEMTRADA?

Before receiving LEMTRADA, tell your healthcare provider if you:

- are taking a medicine called Campath®. Alemtuzumab, the active ingredient in LEMTRADA, is the same drug as Campath.
- have bleeding problems
- have thyroid problems
- have kidney problems
- have a recent history of infection
- have HIV
- 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. It is not known if LEMTRADA passes into your breast milk. 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. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How will I receive LEMTRADA?

- LEMTRADA is given through a needle placed in your vein (IV infusion).
- It takes about 4 hours to receive a full dose of LEMTRADA each day.
- You will receive LEMTRADA over 2 treatment courses.
- You will receive LEMTRADA for 5 days in a row (consecutive) for the first treatment course and then for 3 days in a row (consecutive) about 1 year later for your second treatment course.

What are the possible side effects of LEMTRADA?

LEMTRADA may cause serious side effects including:

- See "What is the most important information I should know about LEMTRADA?"
- **thyroid problems.** Some people who receive LEMTRADA may get thyroid problems including an overactive thyroid (hyperthyroidism) or an underactive thyroid (hypothyroidism). Your healthcare provider will do blood tests to check how your thyroid is working. Call your healthcare provider if you have any of the symptoms of thyroid problems.

Symptoms of **hyperthyroidism** may include:

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

Symptoms of **hypothyroidism** may include:

- unexplained weight gain
- worsening tiredness
- feeling cold
- 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. Symptoms of cytopenias may include:

- weakness
- chest pain
- yellowing of the skin or whites of eyes (jaundice)
- dark urine
- fast heartbeat

Your healthcare provider will do blood tests to check for cytopenias. Call your healthcare provider right away if you have symptoms listed above.

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

- **herpes viral infections.** Some people taking LEMTRADA have an increased chance of getting herpes viral infections. Your healthcare provider will prescribe medicines to reduce your chances of getting these infections. Take these medicines exactly as your healthcare provider tells you to.
- **human papilloma virus (HPV).** Females have an increased chance of getting a cervical HPV infection. If you are a female, you should have an HPV screening each year.
- **tuberculosis.** Your healthcare provider should check you for tuberculosis before you receive LEMTRADA.
- **fungal infections.**
- **listeria.** People who receive LEMTRADA have an increased chance of getting an infection caused by the bacteria listeria. Avoid foods that may be a source for listeria (for example, deli meat, unpasteurized milk and cheese products, or undercooked meat, seafood or poultry) or make sure that the food you eat which may contain listeria is heated well if you receive treatment with LEMTRADA.

Call your healthcare provider right away if you have symptoms of a serious infection, such as fever or swollen glands. You may need to go to the hospital for treatment if you get a serious infection. It is important to tell the healthcare providers that you have received LEMTRADA.

Talk to your healthcare provider before you get vaccinations after receiving LEMTRADA. Certain vaccinations may increase your chances of getting infections.

- **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 of acalculous cholecystitis, which may include:

- 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

The most common side effects of LEMTRADA include:

- rash
- headache
- thyroid problems
- fever
- swelling of your nose and throat (nasopharyngitis)
- nausea
- urinary tract infection
- feeling tired
- trouble sleeping
- upper respiratory tract 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. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

General information about the safe and effective use of LEMTRADA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use LEMTRADA for a condition for which it was not prescribed. Do not give LEMTRADA to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about LEMTRADA. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about LEMTRADA that is written for health professionals.

For more information, go to www.LemtradaREMS.com or call Sanofi Genzyme at 1-855-676-6326.

What are the ingredients in LEMTRADA?

Active ingredient: alemtuzumab

Inactive ingredients: sodium chloride, dibasic sodium phosphate, potassium chloride, potassium dihydrogen phosphate, polysorbate 80, disodium edetate dihydrate, and water for injection.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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Genzyme Corporation

500 Kendall Street

Cambridge, MA 02142

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