PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

LEMTRADA®
(alemtuzumab for injection)

Read this carefully before you start taking **LEMTRADA** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **LEMTRADA**.

Keep this leaflet, Patient Guide and the Patient Alert Card. You should read them before starting LEMTRADA, and before each LEMTRADA treatment course

- It is important that you keep the Card with you during treatment and for 48 months after the last dose of LEMTRADA, since side effects may occur even after you have stopped treatment.
- Show your Card and this package leaflet to any doctor involved in your treatment.

Serious Warnings and Precautions

Infusion reactions
LEMTRADA causes serious and life-threatening infusion reactions. LEMTRADA must be administered in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions. Monitor patients for two hours after each infusion. Make patients aware that serious infusion reactions can also occur after the 2-hour monitoring period.

Stroke
Serious and life-threatening reactions after infusion including stroke (including ischemic and hemorrhagic stroke), bleeding in the lung, heart attack or tears in blood vessels supplying the brain have been reported within 3 days of LEMTRADA administration. Instruct patients to seek immediate medical attention if symptoms of of these conditions occur.

Malignancies
LEMTRADA may cause an increased risk of malignancies, including thyroid cancer, melanoma, and lymphoproliferative disorders. Perform baseline and yearly skin exams.

Autoimmune conditions
Serious and fatal autoimmune immune and mediated conditions including immune thrombocytopenic purpura (low platelets), liver inflammation, liver injury, excessive activation of white blood cells associated with inflammation (Haemophagocytic lymphohistiocytosis (HLH)) and kidney disease have occurred in patients receiving LEMTRADA (see **Autoimmune Side Effects**, below).

Infections
Serious viral, bacterial, protozoan, and fungal infections including deaths have been reported in non-MS patients receiving alemtuzumab therapy (MabCampath®) at higher and more frequent doses than used in MS. Progressive multifocal leukoencephalopathy (PML) can occur as the result of a rare and serious brain infection. PML is a viral infection which causes serious illness or death. PML occurs in patients with leukemia with or without MabCampath treatment, and in patients treated with other MS treatments. Your doctor should monitor you for signs or symptoms of this and any infection. (see **Infections**, below)

What is LEMTRADA used for?

LEMTRADA is used to treat relapsing forms of multiple sclerosis (MS) in adults. LEMTRADA is indicated for the management of adult patients with relapsing remitting multiple sclerosis (RRMS), with highly active disease defined by clinical and imaging features, despite an adequate course of treatment with at least two other disease modifying treatments (DMTs), or where any other DMT is contraindicated or otherwise unsuitable.

Multiple sclerosis is a disease of the central nervous system (brain and spinal cord). In MS your immune system mistakenly attacks the protective layer (myelin) around the nerve fibers of your central nervous system, causing inflammation. When the inflammation causes you to have symptoms this is often called a “relapse” or “attack”. In Relapsing Remitting MS (RRMS) patients experience relapses followed by periods of recovery.

The symptoms you experience depend on which part of your central nervous system is affected. The damage done to your nerves during this inflammation may be reversible, but as your disease progresses the damage may build up and become permanent.

How does LEMTRADA work?

LEMTRADA is a monoclonal antibody. Monoclonal antibodies are proteins which bind to a unique site (called an antigen) on cells. LEMTRADA binds to an antigen, called CD52, which is present at high levels on certain cells of your immune system. LEMTRADA works on your immune system so that it may not attack your nervous system as much.

What are the ingredients in LEMTRADA?

Medicinal ingredients: alemtuzumab

Non-medicinal ingredients: dibasic sodium phosphate, disodium edetate dihydrate, potassium chloride, potassium dihydrogen phosphate, polysorbate 80, sodium chloride, water for injection

LEMTRADA comes in the following dosage forms:

LEMTRADA is provided as a concentrate solution that must be diluted prior to intravenous infusion. It is supplied in single-use vials containing 12 mg of alemtuzumab in 1.2 mL of sterile, preservative-free solution.

Do not use LEMTRADA if you:

- have an allergy to alemtuzumab or any of the other ingredients of LEMTRADA (see above for a list of important non-medicinal ingredients).
- are infected with Human Immunodeficiency Virus (HIV).
- are infected with Tuberculosis.
- have a severe active infection.
- have an active cancer
- have or had a type of rare infection of the brain called progressive multifocal leukoencephalopathy (PML).
- Or if you are using medications that weaken your immune system.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take LEMTRADA. Talk about any health conditions or problems you may have, including if you:

- Are taking a medicine called MabCampath®.
- Have bleeding problems.
- Have thyroid problems.
- Have kidney problems.
- Have a recent history of infection, including tuberculosis.
- Have been vaccinated within 6 weeks before receiving a treatment course of LEMTRADA. After your treatment course with LEMTRADA, consult your doctor if you wish to be vaccinated. Your doctor will determine if it is safe for you to do so.
- Are pregnant or could become pregnant.
- Are breast-feeding or plan to breast-feed.
- Have or had cancer.

Other warnings you should know about:

Pregnancy
If you think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. LEMTRADA is not recommended in pregnant women. Woman who could become pregnant should use effective contraceptive methods during treatment with LEMTRADA and for 4 months after each course of treatment.

If you become pregnant after treatment with LEMTRADA and experience thyroid problems during pregnancy, extra caution is needed. Thyroid problems could be harmful to the baby (see **Autoimmune Side Effects**, below).

Breastfeeding
It is unknown if LEMTRADA can be transferred to a baby through breast milk, but there could be a risk. You should not breast-feed during each course of treatment with LEMTRADA or for 4 months after each treatment course.

LEMTRADA can cause serious side effects including:

Autoimmune side effects
Your body's immune system contains substances called antibodies that help fight infections. Autoimmune side effects are illnesses that occur when the body makes antibodies against itself. LEMTRADA may cause your body to develop antibodies that target certain organs, such as your thyroid. These antibodies may lead to development of autoimmune side effects such as immune thrombocytopenic purpura (ITP, or low platelets), thyroid disorders, or, in rare cases, kidney diseases. No one can predict who will develop an autoimmune side effect. Getting blood tests and knowing the symptoms can help with early diagnosis.

- ***Immune thrombocytopenic purpura (ITP, or low platelets)***: LEMTRADA may cause a condition known as ITP, which results in a decrease in the number of platelets in the blood. Platelets are necessary for normal blood clotting. ITP can cause severe bleeding that, if untreated, may lead to serious health complications and possibly death. If detected early, ITP is usually treatable. Your doctor will order a blood test before starting LEMTRADA and on a monthly basis after your initial treatment course, and continuing for 4 years after your last LEMTRADA infusion. This blood test will help your doctor watch

for changes in your platelet count in order to catch this side effect early. Importantly, ITP may also be detected by certain symptoms that you need to know (see "**Serious Side Effects and What to Do About Them"**, below). Call your doctor immediately if you have any of these signs or symptoms. If you cannot reach your doctor seek immediate medical attention.

- ***Thyroid disorders:*** The thyroid is a gland found in the front of the neck. This gland produces hormones that are important throughout your body. LEMTRADA may cause development of thyroid disorders, including an overactive or underactive thyroid gland. Thyroid disorders are generally treatable, though they may require lifelong treatment. Bulging of the eyes may occur with an overactive thyroid. Your doctor will order a blood test before starting LEMTRADA and every 3 months after your initial treatment course and continuing for 4 years after your last LEMTRADA infusion. This blood test will help your healthcare provider detect thyroid disease early. See "**Serious Side Effects and What to Do About Them"**, below for signs and symptoms of thyroid disorders you should be aware of and what to do should they occur. Call your doctor if you have any of these signs or symptoms.

  Talk to your doctor if you are considering becoming pregnant or if you become pregnant after receiving LEMTRADA, as untreated thyroid disease may cause harm to you or your developing baby.

- ***Kidney diseases***: LEMTRADA may cause a condition known as anti-glomerular basement membrane disease. Anti-glomerular basement membrane disease is an autoimmune side effect that can result in severe damage to the kidneys. It can also damage the lungs, although this was not seen in clinical trials with LEMTRADA. If untreated, anti-glomerular basement membrane disease can cause kidney failure requiring chronic dialysis or transplant and may lead to death. Your healthcare provider will order a blood test and urine test before starting LEMTRADA and on a monthly basis after your initial treatment course and continuing for 4 years after your last LEMTRADA infusion. Both of these tests will help your doctor watch for signs of kidney disease to help catch this side effect early. See "**Serious Side Effects and What to Do About Them"**, below for signs and symptoms of anti-glomerular basement membrane disease you should be aware of and what to do should they occur. If untreated it can cause kidney failure requiring dialysis or transplantation and may lead to death. Call your doctor immediately if you have any of these signs or symptoms. If you cannot reach your doctor seek immediate medical attention.

- ***Other autoimmune conditions***
  Very rarely, patients have experienced autoimmune conditions with **the red blood cells or white blood cells**. This can be diagnosed from the blood checks that you will be having after LEMTRADA treatment. If you develop one of these conditions your doctor will take appropriate measures to treat it.

- ***Inflammation of the gallbladder:*** LEMTRADA may increase your chance of getting inflammation of the gallbladder. This may be a serious medical condition that can be life threatening. You should report to your doctor if you have symptoms such as stomach pain or discomfort, fever, nausea or vomiting.

- ***Haemophagocytic lymphohistiocytosis**:* LEMTRADA may increase the risk of excessive activation of white blood cells associated with inflammation (haemophagocytic lymphohistiocytosis), which can be fatal if not diagnosed and treated early. If you experience multiple symptoms such as fever, swollen glands, bruising, or skin rash, contact your doctor immediately.

Serious infections
LEMTRADA is a medicine that lowers the number of some white blood cells in your blood for a period of time after treatment. These white blood cells generally return to normal levels over time. People with decreased white blood cells may have an increased risk for developing serious infections.

Serious infections may occur if you take LEMTRADA. See "**Serious Side Effects and What to Do About Them"**, below for signs and symptoms of serious infections you should be aware of and what to do should they occur.

You may need to go to the hospital for treatment if you develop a serious infection. It is important to tell the emergency personnel that you have received LEMTRADA.
If you have signs or symptoms of an active infection, it is important that you tell your healthcare provider.

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 medicines. To reduce this risk, you should avoid eating uncooked or undercooked meats, soft cheeses and unpasteurized dairy products two weeks before treatment, during the treatment and for at least one month after LEMTRADA treatment.

Pneumonitis (inflammation of lung tissue) has been reported in LEMTRADA treated patients. Most cases occurred within the first month after treatment with LEMTRADA. You should report to your doctor symptoms like shortness of breath, cough, wheezing, chest pain or tightness and coughing up blood, as these could be caused by pneumonitis.

Infusion reactions
Most patients treated with LEMTRADA will experience side-effects at the time of the infusion or within 24 hours after the infusion. These reactions are described in "**Serious Side Effects and What to Do About Them**" below.

Most infusion reactions are mild, but some serious reactions are possible such as fever, hives, irregular heartbeat, nausea, chest discomfort or low blood pressure. Occasionally allergic reactions are possible.

To reduce these effects, your doctor will give you medication (corticosteroids) before the first 3 infusions of a treatment course. Other treatments to limit these reactions can also be given before the infusion or when you experience symptoms. In addition, you will be observed during the infusion and for at least 2 hours after the infusion has been completed in the clinic. You should know the symptoms of infusion reactions and keep checking for them for at least 1-3 days after each LEMTRADA infusion. In case of serious reactions, it is possible that the infusion may be slowed down or even stopped.

Haemophagocytic lymphohistiocytosis
Treatment with LEMTRADA may increase the risk of excessive activation of white blood cells (cells that fight infections) associated with inflammation (haemophagocytic lymphohistiocytosis), which can be fatal if not diagnosed and treated early. If you experience symptoms such as fever, swollen glands, bruising, or skin rash, contact your doctor immediately.

Adult Onset Still's disease (AOSD)
AOSD is a rare condition that has the potential to cause multi-organ inflammation, with several symptoms such as fever >39°C or 102.2°F 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 healthcare provider immediately.

Acquired hemophilia A
Uncommonly, patients developed a bleeding disorder caused by antibodies that work against factor VIII (a protein needed for normal clotting of blood), called Acquired hemophilia A after receiving LEMTRADA. This condition must be diagnosed and treated immediately. Symptoms of acquired hemophilia A are spontaneous bruising, nose bleeds, painful or swollen joints, other types of bleeding, or bleeding from a cut that may take longer than usual to stop.

Liver inflammation and liver injury
Some patients have developed liver inflammation and liver injury after receiving LEMTRADA. Liver inflammation can be diagnosed from the blood tests that you will be having regularly after LEMTRADA treatment. If you develop nausea, vomiting, abdominal pain, 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.

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 week. 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, memory, and orientation leading to confusion and personality changes
- eyesight
- strength
- balance
- weakness on 1 side of your body
- using your arms

Epstein-Barr virus (EBV)
Patients treated with LEMTRADA have had infections due to a virus called Epstein-Barr virus (EBV), including cases with severe and sometimes fatal liver inflammation. Tell your doctor right away if you have symptoms of infection such as fever, swollen glands, or fatigue.

Sarcoidosis
An immune disorder that can cause inflammation of one or more organs including lungs, lymph nodes, skin or cardiac (sarcoidosis).

Autoimmune Encephalitis
This condition may include symptoms such as behavior and psychiatric changes, movement disorders, short term memory loss or seizures as well as other symptoms resembling an MS relapse.

Vitiligo
Appearance of patchy areas of skin that have lost color. These patches may appear on any area of the body but can be more common on the hands and face.

Other serious reactions occurring shortly after LEMTRADA infusion
Some patients have had serious or life-threatening reactions after LEMTRADA infusion, including bleeding in the lung, heart attack, stroke or tears in blood vessels supplying the brain. Reactions may occur following any of the doses during the treatment course. In the majority of cases reactions occurred within 1-3 days of the infusion. Your doctor will monitor vital signs, including blood pressure, before and during the infusion. Get help right away if you have any of the following symptoms: trouble breathing, chest pain, facial drooping, sudden severe headache, weakness on one side of the body, difficulty with speech or neck pain.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with LEMTRADA:

Interactions between LEMTRADA and other drugs have not been studied. Tell your doctor if you are taking, have recently taken, or might take any other medications, including vaccinations or medications taken without a prescription, such as vitamins and herbal medicines.

Besides LEMTRADA, there are other treatments (including those for MS, or to treat other conditions) which could affect your immune system and so could affect your ability to fight infections. If you have used another MS treatment in the past, your doctor may ask you to stop the other medicine in advance of starting treatment with LEMTRADA.

The safety of immunization with any vaccine, particularly live viral vaccines, following therapy with LEMTRADA has not been studied. It is unknown if LEMTRADA affects your ability to raise a response to a vaccine. If you have not completed the standard required vaccinations, your doctor will consider whether you should have them before your LEMTRADA treatment. In particular, your doctor will consider vaccinating you against chickenpox. Any vaccination will need to be given to you at least 6 weeks prior to starting a LEMTRADA treatment course.

You must not receive live viral vaccines if you have recently received LEMTRADA.

How to take LEMTRADA:

LEMTRADA can only be prescribed by a doctor who is trained in treating neurological conditions. LEMTRADA will be prepared and given to you by a healthcare professional.

Usual dose:

LEMTRADA will be given to you as an infusion into a vein. Each infusion will take approximately 4 hours. For the first treatment course you will receive one infusion per day for 5 days (course 1). One year later

you will receive one infusion per day for 3 days (course 2). Each infusion delivers 12 mg of LEMTRADA. There is no LEMTRADA treatment between the two courses.

Your doctor will order blood and urine tests, and an ECG before starting LEMTRADA. Blood and urine tests will continue for 4 years after your last LEMTRADA infusion. It is important to get this testing done according to the recommended schedule, in order for your healthcare provider to watch for signs of autoimmune side effects so that treatment can occur quickly, if needed.

Overdose:

If you think you, or a person you are caring for, have taken too much LEMTRADA, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose, consult with your doctor. More than one dose should not be given on the same day.

What are possible side effects from using LEMTRADA?

These are not all the possible side effects you may have when taking LEMTRADA. If you experience any side effects not listed here, tell your healthcare professional. Please also see Warnings and Precautions.

Like all medicines, LEMTRADA can cause side effects.

These are the **side effects** that you may experience:

Very common (may affect more than 1 in 10 people)

- **Infusion reactions** that can happen at the time of the infusion or within 24 hours after the infusion: changes in heart rate, headache, rash, rash over your body, fever, hives, chills, itching, reddening of the face and neck, feeling tired, nausea
- Infections: airway infections such as colds and sinus infections, urinary tract infections, herpes infections including herpes zoster infections
- Decrease in white blood cell numbers (lymphocytes, leukocytes)
- Thyroid disorders such as over-active or under-active thyroid gland

Common (may affect up to 1 in 10 people)

- **Infusion reactions** that can happen at the time of the infusion or within 24 hours after the infusion: indigestion, chest discomfort, pain, dizziness, altered taste, difficulty sleeping, difficulty breathing or shortness of breath, low blood pressure, infusion site pain.
- **Infections**: cough, ear infection, flu-like illness, bronchitis, pneumonia, oral thrush or vaginal thrush, shingles, cold sore, swollen or enlarged glands, influenza
- Increase in white blood cells counts such as neutrophils, eosinophils (different types of white blood cells) anaemia, decrease in percentage of red blood cells, easy or excessive bruising or bleeding, swelling of lymph nodes
- pain in the back, the neck, or in arms or legs, muscle pain, muscle spasms, joint pain, painful mouth or throat
- inflammation of the mouth/gums/tongue
- general discomfort, weakness, vomiting, diarrhoea, abdominal pain, gastric flu, hiccups

- abnormal liver test
- heartburn
- abnormalities that can be found during examinations: blood or protein in urine, decreased heart rate, irregular or abnormal heartbeat, high blood pressure, impaired kidney function, white blood cells in urine
- contusion
- MS relapse
- trembling, loss of sensation, burning or prickling sensation
- autoimmune over-active or under-active thyroid gland, thyroid antibodies or goitre (swelling of the thyroid gland in the neck)
- swelling of arms and/or legs
- vision problems, conjunctivitis, eye disease associated with thyroid disease
- sensation of spinning or loss of balance
- feelings of anxiety, depression
- abnormally heavy, prolonged or irregular menstruation
- acne, redness of the skin, excessive sweating, skin discoloration
- nose bleeds, bruises
- hair loss

Uncommon (may affect up to 1 in 100 people)
- **Infections**: tooth infection, tooth abscess, stomach flu, inflammation of the gums, nail fungus, tonsil inflammation, acute sinusitis, bacterial skin infection, pneumonitis,
- athlete's foot
- exaggerated immune response
- abnormal vaginal smear, bacterial vaginal infection
- increased sensation, sensory disturbance such as numbness, tingling and pain
- double vision
- pain in ear
- difficulty swallowing, throat irritation, asthma, productive cough
- decreased weight, weight increase, red blood cell decrease, blood glucose increase, increase in red blood cell size
- constipation, acid reflux, dry mouth
- rectal bleeding
- bleeding of gums
- decreased appetite
- blisters, night sweats, face swelling, dermatitis, eczema, skin lesion
- muscular and bone pain, stiffness, arms or legs discomfort, muscular chest pain
- kidney stones, excretion of ketone bodies in urine
- decreased/weak immune system
- Increase in white blood cells counts: monocytosis

Not known (frequency cannot be estimated from the available data):
- listeriosis/listeria meningitis
- Unusually high fever, swollen/painful joints and/or skin rash which may occur at the same time

LEMTRADA may cause serious side effects, including serious infections and autoimmune side effects such as:
- Vitiligo (patchy loss of skin color in areas of the body)

- Autoimmune Encephalitis (seizures, movement disorders and psychiatric manifestations)

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

Symptom / effect	**Talk to your healthcare professional immediately. If you cannot reach your healthcare professional get immediate medical help.**	
	Only if severe	**In all cases**
VERY COMMON (occurring in at least 1 of every 10 patients)		
Thyroid disorders: **Symptoms including:** • Excessive sweating • Unexplained weight loss • Eye swelling • Nervousness • Fast heartbeat • Unexplained weight gain, • Feeling cold • Worsening tiredness • Constipation		√
COMMON (occurring between 1 and 10 of every 100 patients)		
Serious infections: **Symptoms including:** • Fever • Chills • Swollen glands		√
Immune thrombocytopenic purpura (ITP): **Symptoms, including:** • Easy bruising • Bleeding from a cut that is hard to stop • Heavier menstrual periods than normal • Bleeding from your gums or nose		√

Symptom / effect	Talk to your healthcare professional immediately. If you cannot reach your healthcare professional get immediate medical help.	
	Only if severe	**In all cases**
• Small, scattered spots on your skin that are red, pink, or purple		
UNCOMMON (occurring between 1 and 10 of every 1000 patients)		
Kidney disease: Symptoms including: • Blood in urine (red or tea-colored urine) • Swelling in your legs or feet • Coughing up blood		√
Cytomegalovirus infection (CMV): Symptoms including: • Fever • Chills • Swollen glands		√
UNKNOWN* (Symptoms experienced during Post-Marketing)		
Autoimmune encephalitis (autoimmune brain disorder) : Symptoms including : • seizures • movement disorders • psychotic behaviour /psychiatric manifestations		√
Vitiligo (skin discoloration disorder): Symptoms including : • patchy loss of skin color on hands, face and other areas of the body		√
Pneumonitis (swelling of lung tissue) **Symptoms including:** • shortness of breath • cough • wheezing • chest pain or tightness • coughing or spitting up blood		√
Inflammation of the gallbladder. Symptoms including: • stomach pain or discomfort • fever • nausea or vomiting		√

Symptom / effect	Talk to your healthcare professional immediately. If you cannot reach your healthcare professional get immediate medical help.	
	Only if severe	In all cases
Bleeding in the lung, heart attack, stroke or tears in blood vessels supplying the brain. **Symptoms including:** • trouble breathing • chest pain • facial drooping • sudden severe headache • weakness on one side of the body • difficulty with speech • neck pain		√
Haemophagocytic lymphohistiocytosis (HLH) **Symptoms including:** • fever • swollen lymph nodes • bruising • skin rash		√
Hepatic injury **Symptoms including:** • unexplained nausea • vomiting • abdominal pain • fatigue • anorexia • jaundice • dark urine		√

*Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequencies.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

LEMTRADA must be refrigerated (2° to 8°C) and protected from light. Do not freeze or shake. Do not use after the expiration date on the vial and outer carton.

LEMTRADA contains no preservatives. LEMTRADA should be used within 8 hours after dilution. During that time, the diluted solution may be stored at room temperature (15° to 25°C) or in a refrigerator (2° to 8°C) and must be protected from light.

Keep out of reach and sight of children.

If you want more information about LEMTRADA:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html; the manufacturer's website http://www.sanofi.ca, or by contacting the sponsor, sanofi-aventis Canada Inc. at: 1-800-265-7927.

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