INDICATIONS AND USAGE

LEMTTRA is a CD52-directed cytolytic monoclonal antibody indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS). Because of its safety profile, the use of LEMTRA should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS. (1)

DOSAGE AND ADMINISTRATION

Administer LEMTRA by intravenous infusion over 4 hours for 2 treatment courses:

• First course: 12 mg/day on 5 consecutive days. (2.1)
• Second course: 12 mg/day on 3 consecutive days 12 months after first treatment course. (2.1)

Premedicate with corticosteroids prior to LEMTRA infusion for the first 3 days of each treatment course. (2.3)

Administer antiviral agents for herpetic prophylaxis starting on the first day of LEMTRA dosing and continuing for a minimum of two months after completion of LEMTRA dosing or until CD4+ lymphocyte count is more than 200 cells per microliter, whichever occurs later. (2.3)

Must be diluted prior to administration. (2.4)

Dosage Information

Injection: 12 mg/1.2 mL (10 mg/mL) in a single-use vial. (3)

 CONTRAINDICATIONS

Infection with Human Immunodeficiency Virus. (4)

WARNINGS AND PRECAUTIONS

• Thyroid Disorders: Obtain thyroid function tests prior to initiation of treatment and every 3 months until 48 months after the last infusion. (5.7)
• Other Autoimmune Cytopenias: Monitor complete blood counts monthly until 48 months after the last infusion. (5.8)
• Consider delaying initiation of LEMTRA in patients with active infections until the infection is fully controlled. Do not administer live viral vaccines following a course of LEMTRA. (5.9)

ADVERSE REACTIONS

Most common adverse reactions (incidence ≥ 10% and > interferon beta-1a): rash, headache, pyrexia, nasopharyngitis, nausea, urinary tract infection, fatigue, insomnia, upper respiratory tract infection, herpes viral infection, urticaria, pruritus, thyroid gland disorders, fungal infection, arthralgia, pain in extremity, back pain, diarrhea, sinusitis, oropharyngeal pain, paresthesia, dizziness, abdominal pain, flushing, and vomiting. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Genzyme Corporation at 1-800-745-3119 (option 2) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

USE IN SPECIFIC POPULATIONS

Pregnancy: Based on animal data, may cause fetal harm. (8.1)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved Medication Guide

Revised: 07/2016
WARNING: AUTOIMMUNITY, INFUSION REACTIONS, AND MALIGNANCIES

- LEMTRADA causes serious, sometimes fatal, autoimmune conditions such as immune thrombocytopenia and anti-glomerular basement membrane disease. Monitor complete blood counts with differential, serum creatinine levels, and urinalysis with urine cell counts at periodic intervals for 48 months after the last dose of LEMTRADA [see Warnings and Precautions (5.5)].

- 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 [see Warnings and Precautions (5.2)].

- LEMTRADA may cause an increased risk of malignancies, including thyroid cancer, melanoma, and lymphoproliferative disorders. Perform baseline and yearly skin exams to monitor for melanoma [see Warnings and Precautions (5.3)].

- Because of the risk of autoimmune, infusion reactions, and malignancies, LEMTRADA is available only through restricted distribution under a Risk Evaluation Mitigation Strategy (REMS) Program. Call 1-855-676-6236 to enroll in the LEMTRADA REMS program [see Warnings and Precautions (5.4)].

1 INDICATIONS AND USAGE

LEMTRADA is indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS). Because of its safety profile, the use of LEMTRADA should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

2 DOSAGE AND ADMINISTRATION

2.1 Dosage Information

The recommended dosage of LEMTRADA is 12 mg/day administered by intravenous infusion for 2 treatment courses:

- First Treatment Course: 12 mg/day on 5 consecutive days (60 mg total dose)
- Second Treatment Course: 12 mg/day on 3 consecutive days (36 mg total dose) administered 12 months after the first treatment course.

2.2 Precautions

Patients should complete any necessary immunizations at least 6 weeks prior to treatment with LEMTRADA [see Warnings and Precautions (5.5)].

Prior to LEMTRADA treatment determine whether patients have a history of varicella or have been medically intervened if severe infusion reactions occur. Symptomatic treatment for infusion reactions as needed. Consider immediate discontinuation of the infusion. Follow the steps below to prepare the diluted solution of LEMTRADA for intravenous infusion:

1. Remove the vial from the refrigerated container and visually inspect the vial for particulates or discoloration. Do not administer if the product is cloudy.
2. Gently invert the bag to mix the solution. Ensure the sterility of the prepared solution, because it contains no antimicrobial preservatives. Each vial is for single use only.

Prior to administration, protected diluted LEMTRADA solution from light and store for as long as 8 hours either at room temperature 15°C to 25°C (59°F to 77°F) or keep refrigerated at conditions 2°C to 8°C (36°F to 46°F).

2.5 Infusion Instructions

Infuse LEMTRADA over 4 hours starting within 8 hours after dilution. Extend the duration of infusion if clinically indicated.

Administer LEMTRADA in a setting in which equipment and personnel to appropriately manage anaphylaxis or serious infusion reactions are available [see Warnings and Precautions (5.4)].

Do not add or simultaneously infuse other drug substances through the same intravenous line. Do not administer as an intravenous push or bolus.

Monitor vital signs before the infusion and periodically during the infusion. Provide appropriate symptomatic treatment for infusion reactions as needed. Consider immediate discontinuation of the intravenous infusion if severe infusion reactions occur.

Observe patients for infusion reactions during and for at least 2 hours after each LEMTRADA infusion. Consider longer periods of observation if clinically indicated. Inform patients that they should report symptoms of anaphylaxis or other drug reactions after each infusion because they may indicate a need for prompt medical intervention [see Warnings and Precautions (5.2)].

2.6 Laboratory Testing and Monitoring to Assess Safety

Conduct the following laboratory tests at baseline and at periodic intervals for 48 months following the last treatment course of LEMTRADA in order to monitor for early signs of potentially serious adverse effects:

- Complete blood count (CBC) with differential (prior to treatment initiation and at monthly intervals thereafter)
- Serum creatinine levels (prior to treatment initiation and at monthly intervals thereafter)
- Urinalysis with urine cell counts (prior to treatment initiation and at monthly intervals thereafter)

- A test of thyroid function, such as thyroid stimulating hormone (TSH) level (prior to treatment initiation and every 3 months thereafter)

Conduct baseline and yearly skin exams to monitor for melanoma [see Warnings and Precautions (5.3)].

3 DOSAGE FORMS AND STRENGTHS

Injection: 12 mg/1.2 mL (10 mg/mL) in a single-use vial. LEMTRADA is a clear and colorless to slightly yellow solution that requires dilution prior to intravenous infusion.

4 CONTRAINDICATIONS

LEMTRADA is contraindicated in patients who are infected with Human Immunodeficiency Virus (HIV) because LEMTRADA causes prolonged reductions of CD4+ lymphocyte counts.

5 WARNINGS AND PRECAUTIONS

5.1 Autoimmunity

Treatment with LEMTRADA can result in the formation of autoantibodies and increase the risk of serious autoimmune mediated conditions. In clinical studies LEMTRADA-treated patients experienced thyroid abnormalities (34%), immune thrombocytopenia (2%), and for glomerulonephritis (0.3%) [see Warnings and Precautions (5.2)]. LEMTRADA may increase the risk of other autoimmune conditions because of the broad range of autoimmune formation with LEMTRADA. Monitor complete blood counts with differential, serum creatinine levels, and urinalysis with urine cell counts. Consider treatment in patients at higher risk of autoimmunity [see Warnings and Precautions (5.4)].

5.2 Infusion Reactions

LEMTRADA causes cytokine release syndrome resulting in infusion reactions, some of which may be serious and life threatening. In clinical studies, 92% of LEMTRADA-treated patients experienced infusion reactions. In some patients, infusion reactions were reported more than 24 hours after LEMTRADA infusion. Serious reactions occurred in 3% of patients and included anaphylaxis in 2 patients (including anaphylactic shock), angioedema, bronchospasm, hypotension, chest pain, bradycardia, tachycardia (including atrial fibrillation), transient neurologic symptoms, headache, hearing loss, paresthesia, chest pain, and rash. Other infusion reactions included nausea, urticaria, pruritus, insomnia, chills, flushing, fatigue, dyspnea, pulmonary infiltrates, dysgeusia, dyspnea, dizziness, and pain. In clinical studies, 0.6% of patients with infusion reactions received epinephrine or atropine. During postmarketing use, other serious and sometimes fatal infusion reactions included hypoxia, syncope, acute respiratory distress syndrome, respiratory arrest, myocardial infarction, acute cardiovascular insufficiency, and cardiac arrest have been reported in the treatment of patients with B-CLL, as well as other disorders, generally at higher and more frequent doses than recommended in MS. An oncology patient treated with alemtuzumab had fatal transfusion-associated graft-versus-host disease.

Autoantibodies may be transferred from the mother to the fetus during pregnancy. A case of transient transfer of anti-thyroglobulin receptor antibodies resulting in neonatal Graves’ disease occurred after alemtuzumab treatment in the mother [see Use in Specific Populations (8.1)]. LEMTRADA may increase the risk of other autoimmune conditions because of the broad range of autoimmune formation with LEMTRADA.

5.3 Malignancies

Thyroid cancer

LEMTRADA may increase the risk of thyroid cancer. In controlled clinical studies, 3 of 919 (0.3%) LEMTRADA-treated patients developed thyroid cancer, compared to none in the interferon beta-1a-treated group. However, screening for thyroid cancer was performed more frequently in the LEMTRADA-treated group, because of the higher incidence of autoimmune thyroid disorders in those patients. Two additional cases of thyroid cancer in LEMTRADA-treated patients occurred in uncontrolled studies.

Patients and healthcare providers should monitor for symptoms of thyroid cancer including a new lump or swelling in the neck, pain in the front of the neck, persistent hoarseness or other voice changes, trouble swallowing or breathing, or a constant cough not due to an upper respiratory tract infection. Melanoma

LEMTRADA may increase the risk of melanoma. In uncontrolled studies, 4 of 1486 (0.3%) LEMTRADA-treated patients developed melanoma or melanoma in situ. One of those patients had evidence of locally advanced disease. Perform baseline and yearly skin examinations to monitor for melanoma in patients receiving LEMTRADA.

Lymphoproliferative disorders and lymphoma

Cases of lymphoproliferative disorders and lymphoma have occurred in LEMTRADA-treated patients with MS, including a MALT lymphoma, Castleman’s Disease, and a fatally following treatment of non-Epstein Barr Virus-associated Burkitt’s lymphoma. There are postmarketing reports of Epstein Barr Virus associated lymphoproliferative disorders and lymphomas in patients taking LEMTRADA.

Because LEMTRADA is an immunomodulatory therapy, caution should also be exercised in initiating LEMTRADA in patients with pre-existing or ongoing malignancies. LEMTRADA is available only through a restricted program under a REMS [see Warnings and Precautions (5.4)].
In a controlled clinical trial in patients with MS, one LEMTRADA-treated patient developed ITP that went unresolved prior to the implementation of monthly blood monitoring requirements, and died from intracerebral hemorrhage. Nadir platelet counts ≤20,000 cells per microliter as a result of ITP occurred in 2% of all LEMTRADA-treated patients in clinical studies in MS. Anti-platelet antibodies did not precede ITP onset. ITP has been diagnosed more than 3 years after the last LEMTRADA dose. Symptoms of ITP include easy bruising, petechiae, spontaneous mucocutaneous bleeding (e.g., epistaxis, hemoptysis), and heavier than normal or irregular menstrual bleeding. Hemoptysis may also be indicative of anti-glomerular basement membrane (GBM) disease [see Warnings and Precautions (5.6)], and an appropriate differential diagnosis has to be undertaken. Remind the patient to remain vigilant for symptoms they may experience and to seek immediate medical help if they have any concerns.

Obtain complete blood counts (CBCs) with differential prior to initiation of treatment and at monthly intervals thereafter until 48 months after the last infusion [see Dosage and Administration (2.6)]. After this period of testing should be performed based on clinical findings suggestive of ITP. If ITP is suspected, a complete blood count should be obtained immediately. If ITP onset is confirmed, promptly initiate appropriate medical intervention.

5.6 Glomerular Nephropathies

Glomerular nephropathies occurred in 0.3% of LEMTRADA-treated patients in MS clinical trials. There were 3 cases of membranous glomerulonephritis and 2 cases of anti-glomerular basement membrane (GBM)-disease. There are published and post-marketing cases of MS patients treated with alemtuzumab who developed anti-GBM disease and subsequently developed end stage renal disease requiring renal transplantation. Patients diagnosed up to 40 months after the last dose of LEMTRADA. Urgent evaluation and treatment is required because anti-GBM disease can lead to renal failure requiring dialysis or transplantation and can be life-threatening if left untreated. Clinical manifestations of nephropathy may include elevated serum creatinine levels, hematuria, or proteinuria. As hemoptysis as hemoptysis is a common component of anti-GBM disease but did not occur in clinical trials. Obtain serum creatinine levels and urinalysis with cell counts prior to initiation of treatment and at monthly intervals thereafter until 48 months after the last infusion. After this period of time, testing should be performed based on clinical findings suggestive of nephropathies. If clinically significant changes from baseline in serum creatinine, unexplained hematuria, or proteinuria are observed, perform further evaluation for nephropathies. Early detection and treatment of nephropathies may decrease the risk of poor outcomes.

5.7 Thyroid Disorders

Thyroid disorders occurred in 34% of LEMTRADA-treated patients in clinical studies. Newly diagnosed thyroid disorders occurred throughout the uncontrolled clinical study follow-up period, more than 7 years after the first LEMTRADA dose. Autoimmune thyroid disorders included Graves’ disease, hyperthyroidism and hypothyroidism. Graves’ ophthalmopathy with decreased vision, eye pain, and exophthalmos occurred in 8% of LEMTRADA-treated patients. Two patients required thyroidectomy for orbital decompression. Serious thyroid events occurred in about 2% of LEMTRADA-treated patients in clinical studies and included cardiac and psychiatric events associated with thyroid disease. Of all LEMTRADA-treated patients, 12% had undergone some form of parathyroid surgery. Thyroid disorders pose special risks in women who are pregnant [see Use in Specific Populations (8.1)]. Obtain thyroid function tests, such as TSH levels, prior to initiation of treatment and every 3 months thereafter until 48 months after the last infusion. Continue to test thyroid function after 48 months if clinically indicated.

In patients with an ongoing thyroid disorder, LEMTRADA should be administered only if the potential benefit justifies the potential risks.

5.8 Other Autoimmune Cytopenias

Autoimmune cytopenias such as neutropenia (0.1%), hemolytic anemia (0.2%), and pancytopenia (0.2%) occurred in 3% of LEMTRADA-treated patients in clinical studies in MS. In cases of autoimmune hemolytic anemia, patients tested positive for direct antiglobulin antibodies, and nadir hemoglobin levels ranged from 2.9-8.6 g/dL. Symptoms of autoimmune hemolytic anemia include weakness, chest pain, jaundice, dark urine, and tachycardia. One LEMTRADA-treated patient with autoimmune pancytopenia died from sepsis. During postmarketing use, additional autoimmune cytopenias including fatal autoimmune hemolytic anemia and aplastic anemia have been reported in the treatment of patients with B-CLL as well as other disorders, generally at higher and more frequent doses than recommended in MS. Use CBC results to monitor for cytopenias. Prompt medical intervention is indicated if a cytopenia is confirmed.

5.9 Infections

Infections occurred in 7% of LEMTRADA-treated patients compared to 33% of patients treated with interferon beta-1a in controlled clinical trials in MS up to 2 years in duration. Infections that occurred more often in LEMTRADA-treated patients than interferon beta-1a patients included nasopharyngitis, urinary tract infection, upper respiratory tract infection, sinusitis, herpetic infections, influenza, and bronchitis. Serious infections occurred in 3% of patients treated with LEMTRADA as compared to 1% of interferon beta-1a treated patients. Serious infections in the LEMTRADA group included appendicitis, gastroenteritis, pneumonia, herpes zoster, and tooth infection.

Do not administer live viral vaccines following a course of LEMTRADA. Patients treated with LEMTRADA have altered immunity and may be at increased risk of infection following administration of live viral vaccines.

Consider delaying LEMTRADA administration in patients with active infection until the infection is fully controlled. Concomitant use of LEMTRADA with antineoplastic or immunosuppressive therapies could increase the risk of immunosuppression.

In controlled clinical trials, 16% of LEMTRADA-treated patients developed a herpetic viral infection compared to 3% of interferon beta-1a patients. These events included oral herpetic (8.8%), herpes zoster (4.3%), herpes simplex (1.8%), and genital herpes (1.2%). Serious herpetic infections in LEMTRADA-treated patients included primary varicella (0.1%), herpes zoster (0.2%), and herpes meningitis (0.1%). Administer antiviral agents for herpetic prophylaxis at appropriate suppressive dosing regimen. Administer anti-viral prophylaxis for herpetic viral infections starting on the first day of each treatment course and continue for a minimum of two months following treatment with LEMTRADA or until the CD4+ lymphocyte count is ≥200 cells per microliter, whichever occurs later [see Dosage and Administration (2.3)].

Human Papilloma Virus

Cervical human papilloma virus (HPV) infection, including cervical dysplasia, occurred in 2% of LEMTRADA-treated patients. Annual HPV screening is recommended for female patients.

Tuberculosis

Tuberculosis occurred in patients treated with LEMTRADA and interferon beta-1a in controlled clinical trials. Active and latent tuberculosis cases have been reported in 0.3% of LEMTRADA-treated patients, most often in endemic regions. Perform tuberculosis screening according to local guidelines prior to initiation of LEMTRADA. For patients testing positive in tuberculosis screening, treat by standard medical practice prior to therapy with LEMTRADA.

Fungal Infections

Fungal infections, especially oral and vaginal candidiasis, occurred more commonly in LEMTRADA-treated patients (12%) than in patients treated with interferon beta-1a (3%) in controlled clinical trials in MS.

Listeria Infections

Listeria meningitis has been reported in LEMTRADA-treated patients. Cases of listeriosis meningitis occurred within 1 month of altemumab dosing. The duration of increased risk for listeria meningitis is not known. Patients should avoid or adequately heat foods that are potential sources of Listeria monocytogenes.

Infections in non-MS patients

During postmarketing use, serious and sometimes fatal viral, bacterial, protozoal, and fungal infections, including some due to reactivation of latent infections, have been reported in the treatment of patients with B-CLL, as well as other disorders, generally at higher and more frequent doses than recommended in MS.

Hepatitis

No data are available on the association of LEMTRADA with Hepatitis B virus (HBV) or Hepatitis C virus (HCV) reactivation because patients with evidence of active or chronic infections were excluded from the clinical trials. Consider screening patients at high risk of HBV and/or HCV infection before initiation of LEMTRADA and exercise caution in prescribing LEMTRADA to patients identified as carriers of HBV and/or HCV as these patients may be at risk of irreversible liver damage relative to a potential virus reactivation as a consequence of their pre-existing status.

5.10 Pneumonitis

In clinical studies, 6 of 1217 (0.5%) LEMTRADA-treated patients had pneumonitis of varying severity. Cases of hypersensitivity pneumonitis and pneumonitis with fibrosis occurred in clinical studies. Patients should be advised to avoid certain foods that may contain molds, which may include bakery products and certain dairy products. Administer anti-viral prophylaxis for herpetic viral infections starting on the first day of each treatment course and continue for a minimum of two months following treatment with LEMTRADA or until the CD4+ lymphocyte count is ≥200 cells per microliter, whichever occurs later [see Warnings and Precautions (5.5)]

Drug Products with Same Active Ingredient

LEMTRADA contains the same active ingredient (altemumab) found in CAMPATH®, if LEMTRADA is considered for use in a patient who has previously received CAMPATH, exercise increased vigilance for additive and long-lasting effects on the immune system.

6 ADVERSE REACTIONS

The following serious adverse reactions are described below and elsewhere in the labeling:

• Autoimmunity [see Boxed Warning and Warnings and Precautions (5.1)]
• Infusion reactions [see Boxed Warning and Warnings and Precautions (5.2)]
• Malignancies [see Warnings and Precautions (5.3)]
• Immune Thrombocytopenia [see Warnings and Precautions (5.5)]
• Glomerular Nephropathies [see Warnings and Precautions (5.6)]
• Thyroid Disorder [see Warnings and Precautions (5.7)]
• Other Autoimmune Cytopenias [see Warnings and Precautions (5.8)]
• Infections [see Warnings and Precautions (5.9)]
• Pneumonitis [see Warnings and Precautions (5.10)]

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. In controlled clinical trials (Study 1 and Study 2), a total of 811 patients with relapsing forms of MS received LEMTRADA. A total of 811 patients received 1 course of therapy, and 789 patients received a second course of therapy at 12 months. The overall follow-up in the controlled trials was equivalent to 1622 patient years, with an additional 3411 person-years of follow-up in an open label extension study. The population was 18-55 years of age, 65% were female, and 92% were Caucasian.

Most Common Adverse Reactions

In clinical trials, the most common adverse reactions with LEMTRADA (in at least 10% of patients and more frequently than in interferon beta-1a) were rash, headache, pyrexia, nasopharyngitis, nausea, upper respiratory tract infection, fatigue, and Herpes zoster. Serious clinical reactions in the LEMTRADA group included appendicitis, gastroenteritis, pneumonia, herpes zoster, and tooth infection.

Table 1 lists adverse reactions occurring in ≥5% of LEMTRADA-treated patients in Study 1 and 2 and at the same or at a higher rate than interferon beta-1a.
Table 1: Adverse Reactions in the Pooled 2-Year Active-Controlled Studies in Patients with Relapsing-Remitting Multiple Sclerosis

<table>
<thead>
<tr>
<th>Reaction</th>
<th>LEMTRADA (N=811)</th>
<th>Interferon beta-1a 44 mcg (N=368)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>%</td>
<td>%</td>
</tr>
<tr>
<td>Rash</td>
<td>53</td>
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</tr>
<tr>
<td>Headache</td>
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<td>Nausea</td>
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</tr>
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<td>Herpes viral infection</td>
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<td>3</td>
</tr>
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<td>Urticaria</td>
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<td>Pruritus</td>
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<td>Thyroid gland disorders</td>
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<td>Cough</td>
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<td>Blood in urine</td>
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<tr>
<td>Abnormal uterine bleeding</td>
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</table>

6.2 Lymphopenia

Nearly all (99.3%) patients treated with LEMTRADA in MS clinical trials experienced lymphopenia. The lowest lymphocyte counts occurred approximately by 1 month after each course of treatment. The mean lymphocyte count at 1 month after LEMTRADA treatment was 0.25 x 10^9/L (range 0.02-2.30 x 10^9/L) and 0.32 (0.02-1.81 x 10^9/L) for treatment courses 1 and 2, respectively. Total lymphocyte counts increased to reach the lower limit of normal in approximately 40% of patients by 6 months after each LEMTRADA treatment course and approximately 80% of patients by 12 months after each course [see Clinical Pharmacology (12.2)].

6.3 Suicidal Behavior or Ideation

In clinical studies, 0.6% of patients in both the LEMTRADA and interferon beta-1a groups had events of attempted suicide or suicidal ideation. There were no completed suicides in either clinical study treatment group. Suicidal behavior or ideation occurred in patients with or without a history of a psychiatric or thyroid disorder. Advise patients to report immediately any symptoms of depression or suicidal ideation to the prescriber. Among patients who had completed treatment, the rate of suicidal ideation was 0.7% before treatment and 0.3% at the end of the study. Suicidal ideation was observed in 1.8% of LEMTRADA-treated patients and 0.8% of interferon beta-1a-treated patients. Suicidal ideation occurred in 3.6% of patients before treatment and in 1.6% of patients at the end of the study.

6.4 Immunogenicity

As with all therapeutic proteins, there is potential for immunogenicity. Using an enzyme-linked immunosorbent assay (ELISA) and a competitive binding assay, anti-alemtuzumab binding antibodies were detected in 62%, 67%, and 29% of LEMTRADA-treated patients, at months 1, 3, 12 (Course 1) as well as 83%, 85%, and 75% of LEMTRADA-treated patients at months 13, 15, and 24 (Course 2). Samples that tested positive for binding antibodies were further evaluated for evidence of in vitro inhibition using a flow cytometry assay. Neutralizing antibodies were detected in 67%, 46%, and 5% of positive binding antibody patients at months 1, 3, 12 (Course 1) as well as 94%, 88%, and 45% of positive binding antibody patients at months 13, 15, and 24 (Course 2). Anti-alemtuzumab antibodies were associated with decreased alemutuzumab concentration during Course 2 but not Course 1. There was no evidence from clinical trials that the presence of binding or inhibitory anti-alemtuzumab antibodies had a significant effect on clinical outcomes, total lymphocyte count, or adverse events.

The incidence of antibodies is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including inhibitory antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to LEMTRADA with the incidence of antibodies to other products may be misleading.

6.5 Postmarketing Experience

The following adverse reactions, not described elsewhere, were identified during post-approval use of alemtuzumab (CAMPATH) for the treatment of B-cell chronic lymphocytic leukemia (B-CLL), as well as for the treatment of other disorders, generally at higher and more frequent doses (e.g., 50 mg) than that recommended in the treatment of MS. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Cardiac Disorders

Congestive heart failure, cardiomyopathy, and decreased ejection fraction in non-MS patients previously treated with potentially cardiotoxic agents.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C

There are no adequate and well-controlled studies in pregnant women. LEMTRADA was embryotoxic in pregnant huCD52 transgenic mice when administered during organogenesis. Auto-antibodies may develop after administration of LEMTRADA. Placental transfer of anti-thyroid antibodies resulting in neonatal Graves’ disease has been reported. LEMTRADA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Animal Data

When LEMTRADA was administered to pregnant huCD52 transgenic mice during organogenesis (gestation days [GD] 6-10 or GD 11-15) at doses of 3 or 10 mg/kg IV, no teratogenic effects were observed. However, there was an increase in embryolethality (increased post-implantation loss and the number of dams with all fetuses dead or resorbed) in pregnant animals dosed during GD 11-15.

In a separate study in pregnant huCD52 transgenic mice, administration of LEMTRADA during organogenesis (GD 6-10 or GD 11-15) at doses of 3 or 10 mg/kg/IV, decreases in B lymphocytes and T-lymphocyte populations were observed in the offspring at both doses tested. The effects of LEMTRADA, administered during organogenesis, on postnatal development have not been adequately assessed.

Clinical Considerations

To avoid in utero exposure to LEMTRADA, women of child bearing potential should use effective contraceptive measures when receiving a course of treatment with LEMTRADA and for 4 months following that course of treatment.

LEMTTRADA induces persistent thyroid disorders (see Warnings and Precautions [5.7]). Untreated hypothyroidism in pregnant women increases the risk for miscarriage and may have effects on the fetus including mental retardation and dwarfism. In mothers with Graves’ disease, maternal thyroid stimulating hormone receptor antibodies can be transferred to a developing fetus and can cause neonatal Graves’ disease. In a patient who developed Graves’ disease after treatment with alemtuzumab, placental transfer of anti-thyrotropin receptor antibodies resulted in neonatal Graves’ Disease with thyroid storm in her infant who was born 1 year after alemtuzumab dosing (see Warnings and Precautions [5.1]).

8.2 Nursing Mothers

Alemutuzumab was detected in the milk of lactating mice administered 10 mg/kg LEMTRADA on Days 8 through 12 postpartum. Serum levels of alemutuzumab were similar in lactating mice and offspring on Day 13 postpartum, and were associated with evidence of pharmacological activity (decrease in lymphocyte counts) in the offspring.

It is not known whether alemtuzumab is excreted in human milk. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants from LEMTRADA, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

8.3 Pediatric Use

Safety and effectiveness in pediatric patients less than 17 years of age have not been established. Use of LEMTRADA is not recommended in pediatric patients due to the risks of autoimmunity, infusion reactions, and because it may increase the risk of malignancies (thyroid, melanoma, lymphoproliferative disorders, and lymphoma) [see Warnings and Precautions (5.1), (5.2), (5.3)].

8.4 Geriatric Use

Clinical studies of LEMTRADA did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently than younger patients.
Study 1 was a 2-year randomized, open-label, rater-blinded, active comparator (interferon beta-1a 44 mcg micrograms administered subcutaneously three times a week) controlled study in patients with RRMS. Patients entering Study 2 had EDSS scores of 3 or less and no prior treatment for multiple sclerosis. Patients were randomized to receive LEMTRADA (N=376) or interferon beta-1a (N=187). At baseline, the mean age was 33 years, the mean disease duration was 2 years, and the mean EDSS score was 0.39.

The clinical outcome measures were the annualized relapse rate (ARR) over 2 years and the time to confirmed disability progression, as defined in Study 1. The MRI outcome measure was the change in T2 lesion volume. The results for Study 2 are shown in Table 3.

![Image](Figure1.png)
16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied
Each LEMTRADA carton (NDC: 58468-0200-1) contains 1 single-use vial that delivers 12 mg/1.2 mL (10 mg/mL). The vial stopper is not made with natural rubber latex.

LEMTRADA is a sterile, clear and colorless to slightly yellow solution for infusion, containing no antimicrobial preservatives.

16.2 Storage and Handling
Store LEMTRADA vials at 2°C to 8°C (36°F to 46°F). Do not freeze or shake. Store in original carton to protect from light.

17 PATIENT COUNSELING INFORMATION
Advise the patient to read the FDA-approved patient labeling (Medication Guide).

Autoimmunity
 Advise patients to contact their healthcare provider promptly if they experience any symptoms of potential autoimmune disease. Give examples of important symptoms such as bleeding, easy bruising, petechiae, purpura, hematuria, edema, jaundice, or hemoptysis [see Warnings and Precautions (5.1)].
 Advise patients of the importance of monthly blood and urine tests for 48 months following the last course of LEMTRADA to monitor for signs of autoimmunity because early detection and prompt treatment can help prevent serious and potentially fatal outcomes associated with these events. Advise patients that monitoring may need to continue past 48 months if they have signs or symptoms of autoimmunity.
 Advise patients that LEMTRADA may cause hyperthyroid or hypothyroid disorders.
 Advise patients to contact their healthcare provider if they experience symptoms reflective of a potential thyroid disorder such as unexplained weight loss or gain, fast heartbeat or palpitations, eye swelling, constipation, or feeling cold.
 Advise women of childbearing potential of the risks of pregnancy with concomitant thyroid disease.
 Advise women of childbearing potential to discuss pregnancy planning with their doctor.

Infusion Reactions
 Advise patients that infusion reactions can occur after they leave the infusion center [see Warnings and Precautions (5.2)]
 Instruct the patient to remain at the infusion center for 2 hours after each LEMTRADA infusion, or longer at the discretion of the physician. Advise patients that symptoms of infusion reactions may occur after they leave the infusion center and to report these symptoms to their doctor.
 Advise patients to contact their healthcare provider promptly if they experience infusion reactions, which include swelling in the mouth or throat, difficulty breathing, weakness, abnormal heart rate (fast, slow, or irregular), chest pain, and rash.

Malignancies
 Advise patients that LEMTRADA may increase their risk of malignancies including thyroid cancer and melanoma [see Warnings and Precautions (5.3)].
 Advise patients to report symptoms of thyroid cancer, including a new lump or swelling in the neck, pain in the front of the neck, hoarseness or other voice changes that do not go away, trouble swallowing or breathing, or a constant cough not due to a cold.
 Advise patients that they should have baseline and yearly skin examinations.

LEMTRADA REMS Program
 LEMTRADA is available only through a restricted program called the LEMTRADA REMS Program [see Warnings and Precautions (5.4)]. Inform the patient of the following notable requirements:
 • Patients and providers must be enrolled in the program.
 • Patients must comply with the ongoing monitoring requirements.
 • Patients must report any side effects or symptoms to their doctor.
 LEMTRADA is available only at certified infusion centers participating in the program. Therefore, provide patients with information on the LEMTRADA REMS Program in order to locate an infusion center.
 Advise patients to read the LEMTRADA REMS material for patients, 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.
 Advise patients to contact the LEMTRADA REMS Patient Safety Information Card with them in case of an emergency.

Infections
 Advise patients to contact their healthcare provider if they develop symptoms of serious infection such as fever or swollen glands [see Warnings and Precautions (5.8)].
 Advise patients to complete any necessary immunizations at least 6 weeks prior to treatment with LEMTRADA [see Dosage and Administration (2.2)]. Advise patients that they should talk to their healthcare provider before taking any vaccine after recent treatment with LEMTRADA [see Warnings and Precautions (5.9)].
 Advise patients to take their prescribed medication for herpes prophylaxis as directed by their healthcare provider [see Warnings and Precautions (5.9)].
 Advise patients that yearly HPV screening is recommended [see Warnings and Precautions (5.9)].
 Advise patients to avoid or adequately heat foods that are potential sources of Listeria monocytogenes if they have had a recent course of LEMTRADA. The duration of increased risk for listeria infection after LEMTRADA administration is not known [see Warnings and Precautions (5.9)].

Pneumonia
 Advise patients that pneumonia has been reported in patients treated with LEMTRADA [see Warnings and Precautions (5.10)]. Advise patients to report symptoms of lung disease such as shortness of breath, cough, wheezing, chest pain or tightness, and hemoptysis.

Concomitant Use of Campath
 Advise patients that alemtuzumab is the same drug as Campath for use in B-CLL. Patients should inform their healthcare provider if they have taken Campath [see Warnings and Precautions (5.11)].

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Genzyme Corporation
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Cambridge, MA 02142
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MEDICATION GUIDE
LEMTRADA® (lem-TRA-da)
(alemtuzumab)
Injection for intravenous infusion

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

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.

- **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

  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_
  - _stress ulcers_
  - _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 healthcare provider 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](http://www.LemtradaREMS.com) or call 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.