7001141

**Package leaflet: Information for the patient**

# LEMTRADA® 12 mg concentrate for solution for infusion

alemtuzumab

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

## Is this leaflet hard to see or read? Phone 0800 035 2525 for help

**Read all of this leaflet carefully before you are administered this medicine because it contains important information for you.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If you get any side-effects talk to your doctor. This includes any possible side-effects not listed in this leaflet. See section 4.

**What is in this leaflet**



## 1. What LEMTRADA is and what it is used for

LEMTRADA contains the active substance alemtuzumab, which is used to treat a form of multiple sclerosis (MS) in adults, called relapsing remitting multiple sclerosis (RRMS). LEMTRADA does not cure MS, but it can reduce the number of MS relapses. It can also help to slow down or reverse some of the signs and symptoms of MS. In clinical studies, patients treated with LEMTRADA had fewer relapses and were less likely to experience worsening of their disability compared to patients treated with a beta-interferon injected multiple times per week.
LEMTRADA is used if your MS is highly active despite that you have been treated with at least one other medicine for MS or if your MS is rapidly evolving.

**What is multiple sclerosis?**
MS is an autoimmune disease that affects the central nervous system (brain and spinal cord). In MS your immune system mistakenly attacks the protective layer (myelin) around the nerve fibres, causing inflammation. When the inflammation causes symptoms this is often called an "attack" or a "relapse". In RRMS patients experience relapses followed by periods of recovery.

The symptoms you experience are determined by 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 accumulate and become permanent.

**How LEMTRADA works**
LEMTRADA adjusts your immune system to limit its attacks on your nervous system.

## 2. What you need to know before you are administered LEMTRADA

**Do not use LEMTRADA:**
- if you are allergic to alemtuzumab or any of the other ingredients of this medicine (listed in section 6).
- if you are infected with human immunodeficiency virus (HIV).
- if you are suffering from a serious infection
- if you have any of the following conditions:
  - other autoimmune disease besides multiple sclerosis
  - uncontrolled high blood pressure
  - history of tears in blood vessels supplying the brain
  - history of stroke
  - history of heart attack or chest pain
  - history of bleeding disorder

**Warnings and precautions**

Talk to your doctor before LEMTRADA is given. After having a course of treatment with LEMTRADA you may be at greater risk of developing other autoimmune conditions, or experiencing serious infections. It is important you understand these risks and how to monitor for them. You will be given a Patient Alert Card and a Patient Guide with further information. It is important that you keep the Patient Alert Card with you during treatment and for 4 years after your last infusion with LEMTRADA, because side effects may occur many years after treatment. When you have medical treatment, even if it is not for your MS, show the Patient Alert Card to the doctor.

Your doctor will perform blood tests before you start treatment with LEMTRADA. These tests are done to see whether you may take LEMTRADA. Your doctor will also want to make sure that you do not have certain medical conditions or disorders before you start your treatment with LEMTRADA.

- **Autoimmune conditions**

Treatment with LEMTRADA may increase the risk for autoimmune conditions. These are conditions in which your immune system mistakenly attacks your body. Information about some specific conditions that have been seen in MS patients who have been treated with LEMTRADA is provided below.

The autoimmune conditions can occur many years after treatment with LEMTRADA. Therefore, regular blood and urine tests are needed until 4 years after your last infusion. Testing is needed even if you are feeling well and your MS symptoms are under control. There are certain signs and symptoms that you should look out for yourself. In addition, these conditions may occur beyond 4 years, therefore, you must continue to look for signs and symptoms, even after you no longer need to do monthly blood and urine tests. Details about the signs and symptoms, testing, and actions you need to take are described in sections 2 and 4 – *autoimmune conditions*.

More helpful information about these autoimmune conditions (and the testing for them) can be found in the **LEMTRADA Patient Guide**.

  - **Acquired haemophilia 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. This condition must be diagnosed and treated immediately. Symptoms of acquired hemophilia A are described in section 4.

  - **Immune Thrombocytopenic Purpura (ITP)**

Commonly, patients have developed a **bleeding disorder** caused by a low level of blood platelets, called immune thrombocytopenic purpura (ITP). This must be diagnosed and treated early, as otherwise the effects can be **serious or even fatal**. Signs and symptoms of ITP are described in section 4.

  - **Kidney disease (such as anti-GBM disease)**

Rarely, patients have experienced autoimmune related problems with their **kidneys**, such as anti-glomerular basement membrane disease (anti-GBM disease). Signs and symptoms of kidney disease are described in section 4. If untreated it can cause kidney failure requiring dialysis or transplantation, and may lead to death.

  - **Thyroid disorders**

Very commonly, patients have experienced an autoimmune disorder of the **thyroid gland** affecting its ability to make or control hormones that are important for your metabolism.
LEMTRADA may cause different types of thyroid disorders, including:
- **Over-active thyroid gland** (hyperthyroidism) when the thyroid produces too much hormone
- **Under-active thyroid gland** (hypothyroidism) when the thyroid does not produce enough hormone.

Signs and symptoms of thyroid disorders are described in section 4.

If you develop a thyroid disorder, in most cases you will need to be treated for the rest of your life with medicines to control your thyroid disorder, and in some cases your thyroid gland may have to be removed.

It is very important that you are properly treated for a thyroid disorder, especially if you become pregnant after using LEMTRADA. Having an untreated thyroid disorder could harm your unborn baby, or harm your baby after birth.

  - **Liver inflammation**

Some patients have developed liver inflammation after receiving LEMTRADA. Liver inflammation can be diagnosed from the blood tests that you will be having regularly after LEMTRADA treatment. If you develop one or more of the following symptoms report this to your doctor: nausea, vomiting, abdominal pain, fatigue, loss of appetite, yellow skin or eyes, dark urine, or bleeding or bruising more easily than normal.

  - **Thrombotic thrombocytopenic purpura (TTP)**

A blood clotting disorder called Thrombotic Thrombocytopenic Purpura (TTP), can occur with LEMTRADA. Blood clots form in blood vessels and can happen in the entire body. Get medical help right away if you have any of the following symptoms: skin or mouth bruising that may appear as red pinpoint dots, with or without unexplained extreme tiredness, fever, confusion, speech changes, yellowing of the skin or eyes (jaundice), low amount of urine, dark colored urine. It is advised to seek medical attention urgently as TTP can be fatal (see section 4 'Possible side effects').

  - **Sarcoidosis**

There have been reports of an immune system disorder (sarcoidosis) in patients treated with LEMTRADA. Symptoms can include persistent dry cough, shortness of breath, chest pain, fever, lymph node swelling, weight loss, skin rashes, and blurred vision.

  - **Autoimmune Encephalitis**

Autoimmune encephalitis (an immune mediated brain disorder), can occur after receiving LEMTRADA. This condition may include symptoms such as behavioural and/or psychiatric changes, short term memory loss or seizures. The symptoms may resemble an MS relapse. If you develop one or more of these symptoms contact your doctor.

  - **Other autoimmune conditions**

Uncommonly, patients have experienced autoimmune conditions involving **red blood cells or white blood cells**. These can be diagnosed from the blood tests that you will be having regularly after LEMTRADA treatment. If you develop one of these conditions your doctor will tell you, and take appropriate measures to treat it.

- **Infusion reactions**

Most patients treated with LEMTRADA will experience side-effects at the time of the infusion or within 24 hours after the infusion. To try to reduce infusion reactions, your doctor will give you other medicine(s) (see section 4 – *infusion reactions*).

- **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, coughing up blood, chest pain, facial drooping, sudden severe headache, weakness on one side of the body, difficulty with speech or neck pain.

- **Haemophagocytic lymphohistiocytosis**

Treatment with 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.

- **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.

- **Infections**

Patients treated with LEMTRADA are at a higher risk of getting a **serious infection** (see section 4 – *infections*). In general, the infections can be treated with standard medicines.

In order to reduce the chance of getting an infection, your doctor will check if other medicines you are taking might be affecting your immune system. Therefore, **it is important to tell your doctor about all medicines you are taking**.

Also, tell your doctor if you are suffering from a serious infection before the start of your LEMTRADA treatment as **your doctor should delay the treatment until the infection is resolved.**

Patients treated with LEMTRADA are at a higher risk of developing herpes infection (e.g. **a cold sore**). In general, once a patient has had a herpes infection, they have an increased risk of developing another one. It is also possible to develop a herpes infection for the first time. It is recommended that your doctor prescribes a medicine to reduce the chance of developing a herpes infection, which should be taken on the days that you receive LEMTRADA treatment, and for one month following the treatment.

In addition, infections which can result in **abnormalities of the cervix** (the neck of the womb) are possible. Therefore, it is recommended that all female patients have an annual screening performed, such as a cervical smear. Your doctor will explain to you what tests you will need.

Infections with a virus called **cytomegalovirus** have been reported in patients treated with LEMTRADA. Most cases occurred within two months of alemtuzumab dosing. Tell your doctor right away if you have symptoms of infection such as fever, or swollen glands.

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.

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.

If you live in a region where **tuberculosis** infections are common, you may be at greater risk of infection with tuberculosis. Screening for tuberculosis will be arranged by your doctor.

If you are a carrier of **hepatitis B or hepatitis C infection** (these affect the liver), extra caution is needed before you receive LEMTRADA treatment as it is unknown if treatment could lead to activation of the hepatitis infection which could subsequently damage your liver.

There have been cases of a rare brain infection called PML (progressive multifocal leukoencephalopathy) in patients who have been given Lemtrada. PML has been reported in patients with other risk factors, specifically prior treatment with MS products associated with PML.
PML may lead to severe disability over weeks or months and may be fatal.
Symptoms may be similar to a relapse of MS and include progressive weakness or clumsiness of limbs, disturbance of vision, speech difficulties or changes in thinking, memory, and orientation leading to confusion and personality changes. It is important to inform your relatives or caregivers about your treatment, since they may notice symptoms that you are not aware of. Contact your doctor immediately if you develop any symptoms suggestive of PML.

- **Pneumonitis and pericarditis**

Pneumonitis (inflammation of lung tissue) has been reported in LEMTRADA treated patients. Most cases occurred within the first month after treatment with LEMTRADA. Cases of pericardial effusion (collection of fluid around the heart) and pericarditis (inflammation of the lining around the heart) have also been reported in patients treated 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, pericardial effusion or pericarditis.

- **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.

- **Previously diagnosed cancer**

If you have been diagnosed with cancer in the past, please inform your doctor about it.

- **Vaccines**

It is not known if LEMTRADA affects your 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 if you have never had it. Any vaccination will need to be given to you at least 6 weeks before starting a LEMTRADA treatment course.

You must NOT receive certain types of vaccines (**live viral vaccines**) if you have recently received LEMTRADA.

**Children and adolescents**
LEMTRADA is not intended to be used in children and adolescents below 18 years old as it has not been studied in MS patients below 18 years old.

**Other medicines and LEMTRADA**
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines (including any vaccinations or 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 are using such a medicine, your doctor may ask you to stop this medicine before starting treatment with LEMTRADA.

**Pregnancy**
If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before being given this medicine.

Women who are able to conceive have to use effective contraception during each treatment course with LEMTRADA and for 4 months after each course of treatment.

If you become pregnant after treatment with LEMTRADA and experience a thyroid disorder during pregnancy, extra caution is needed. Thyroid disorders could be harmful to the baby (see section 2 *Warnings and precautions – autoimmune conditions*).

**Breast-feeding**
It is unknown if LEMTRADA can be transferred to a baby through breast milk, but there is a possibility that it could be. It is recommended that you do not breast-feed during each course of treatment with LEMTRADA and for 4 months after each treatment course. However, there may be benefits of breast milk (which can help protect a baby from infections), so talk to your doctor if you are planning to breast-feed your baby. He/she will advise you what is right for you and your baby.

**Fertility**
During your treatment course and for 4 months afterwards, you may have LEMTRADA in your body. It is not known if LEMTRADA will have an effect on fertility during this period. Talk to your doctor if you are thinking about trying to become pregnant. There is no evidence that LEMTRADA has an impact on male fertility.

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**The following information is intended for healthcare professionals only:**

**Information on risk minimisation – autoimmune conditions**

- It is extremely important that your patient understands the commitment to having periodic testing performed (for 4 years after last infusion) even if they are asymptomatic and their MS disease is well controlled.
- Together with your patient you need to plan and manage their periodic monitoring.
- If non-compliant, patients may need further counseling to highlight the risks of missing scheduled monitoring tests.
- You should monitor their test results and remain vigilant for symptoms of adverse events.
- Review the LEMTRADA Patient Guide and Package Leaflet with your patient. Remind the patient to remain vigilant for symptoms related to autoimmune conditions, and to seek medical help if they have any concerns.

Educational Materials for Healthcare Providers are also available:

- LEMTRADA Health Care Professional Guide
- LEMTRADA Training Module
- LEMTRADA Prescriber's Checklist

Read the summary of product characteristics for more information.

**Information on preparing to administer LEMTRADA and patient monitoring**

- Patients should be premedicated with corticosteroids immediately prior to LEMTRADA infusion for the first 3 days on any treatment course. Pretreatment with antihistimines and/or antipyretics prior to LEMTRADA administration may also be considered.
- An oral anti-herpes agent should be administered to all patients during and for 1 month following treatment. In clinical trials, patients were administered aciclovir 200 mg twice a day or equivalent.

**Driving and using machines**
Many patients experience side effects at the time of the infusion or within 24 hours after the infusion with LEMTRADA, and some of these, for example dizziness, could make it unsafe to drive or use machines. If affected, stop these activities until you feel better.

**LEMTRADA contains potassium and sodium**
This medicine contains less than 1 mmol **potassium** (39 mg) per infusion, i.e. it is essentially 'potassium- free'.
This medicine contains less than 1 mmol **sodium** (23 mg) per infusion, i.e. it is essentially 'sodium- free'.

## 3. How LEMTRADA will be administered

Your doctor will explain to you how LEMTRADA will be given. Ask your doctor if you have any questions.

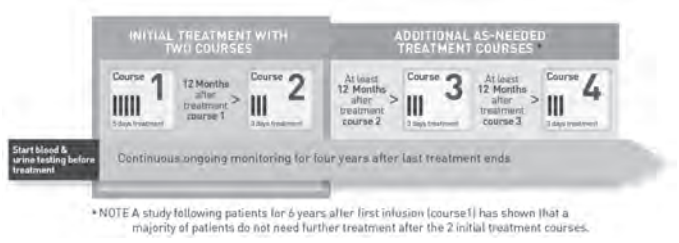
**The initial treatment** you will receive will consist of one infusion per day for 5 days (course 1) and one infusion per day for 3 days one year later (course 2).
There is no LEMTRADA treatment between the two courses. Two treatment courses may reduce MS activity for up to 6 years.

Some patients, if they have symptoms or signs of MS disease after the initial two courses, may receive one or two additional treatment courses consisting of one infusion per day for 3 days . These additional treatment courses may be administered twelve months or more after the prior treatments.

The maximum daily dose is one infusion.

LEMTRADA will be given to you as an infusion into a vein. Each infusion will take approximately 4 hours. Monitoring for side effects and regular testing must continue for 4 years after the last infusion.

To help you better understand the duration of the effects of treatment and the length of required follow-up, please refer to the diagram below.



*NOTE A study following patients for 6 years after first infusion (course1) has shown that a majority of patients do not need further treatment after the 2 initial treatment courses.

**Follow-up after treatment with LEMTRADA**
Once you have received LEMTRADA, you will need to undergo regular tests to ensure that any potential side effects can be diagnosed and treated promptly. These tests must continue until 4 years after your last infusion and are described in section 4 *most important side effects*.

**If you are given more LEMTRADA than you should receive**
Patients who were accidentally given too much LEMTRADA in one infusion have experienced serious reactions, such as headache, rash, low blood pressure or increased heart rate. Doses higher than the recommended dose may result in more serious or longer lasting infusion reactions (see section 4) or a stronger effect on the immune system. The treatment consists of stopping LEMTRADA administration and treating the symptoms.

**Missed LEMTRADA doses**
It is unlikely that your dose would be missed since it is administered by a health care professional. Nevertheless, please note that in case of missed dose, this should not be given on the same day as a scheduled dose.

If you have any further questions on the use of this medicine, ask your doctor.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The **most important side effects** are the **autoimmune conditions** described in section 2 which include:
- **Acquired haemophilia A (a type of bleeding disorder),** (uncommon - may affect up to 1 in 100 people): may show as 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.
- **ITP (bleeding disorders),** (common – may affect up to 1 in 10 people): may show as small scattered red, pink or purple spots on your skin; easy bruising; bleeding from a cut that is harder to stop; heavier, longer or more frequent menstrual periods than normal; bleeding between menstrual periods; bleeding from your gums or nose that is new or takes longer than usual to stop; or coughing up blood.
- **Thrombotic thrombocytopenic purpura (TTP),** (rare-may affect up to 1 in 1,000 people): may show as skin or mouth bruising, that may appear as red pinpoint dots, with or without unexplained extreme tiredness, fever, confusion, speech changes, yellowing of the skin or eyes (jaundice), low amount of urine, dark colored urine.
- **kidney disorders**, (rare – may affect up to 1 in 1,000 people): may show as blood in the urine (your urine may be red or tea-coloured), or as swelling in your legs or feet. It can also lead to damage of your lungs, which can result in coughing up blood.

**If you notice any of these signs or symptoms for bleeding or kidney disorders, call your doctor immediately to report the symptoms. If you cannot reach your doctor, you must seek immediate medical attention.**

- **thyroid disorders** (very common – may affect more than 1 in 10 people): may show as excessive sweating; unexplained weight-loss or gain; eye swelling; nervousness; fast heartbeat; feeling cold; worsening tiredness; or newly occurring constipation.
- **red and white blood cells disorders** (uncommon – may affect up to 1 in 100 people): diagnosed from your blood tests.
- **sarcoidosis** (uncommon – may affect up to 1 in 100 people): symptoms can include persistent dry cough, shortness of breath, chest pain, fever, lymph swelling, weight loss, skin rashes, and blurred vision.
- **autoimmune encephalitis** (uncommon – may affect up to 1 in 100 people): may include symptoms such as behavioural and/or psychiatric changes, short term memory loss or seizures. The symptoms may resemble an MS relapse.

All of these serious side effects can start many years after you have received LEMTRADA. **If you notice any of these signs or symptoms, call your doctor right away to report them.** You will also have regular blood and urine tests to ensure that if you develop any of these conditions, they **are treated promptly**.

**Summary of tests you will have for autoimmune conditions:**

| Test | When? | For how long? |
|---|---|---|
| **Blood test** (to diagnose all important serious side effects listed above) | **Before treatment starts and every month after treatment** | **Until 4 years after your last LEMTRADA infusion** |
| **Urine test** (additional test to diagnose kidney disorders) | **Before treatment starts and every month after treatment** | **Until 4 years after your last LEMTRADA infusion** |

After this time, if you have symptoms of ITP, acquired haemohilia A, TTP, kidney or thyroid disorders, your doctor will perform more tests. You should also continue looking for signs and symptoms of side effects beyond four years as detailed in your patient guide, and you should continue carrying the Patient Alert Card with you.

Another side effect is an **increased risk of infections** (see below for information on how often patients experience infections). In most cases, these are mild but **serious infections** can occur.

**Tell your doctor right away** if you have any of these signs of infection
- fever and/or chills
- swollen glands

To help reduce the risk of some infections your doctor may consider giving you vaccination against chickenpox and/or other vaccinations that they think are necessary for you (see section 2: *What you need to know before you are administered LEMTRADA - Vaccines*). Your doctor can also prescribe a medicine for cold sores (see section 2: *What you need to know before you are administered LEMTRADA – Infections*).

The **most frequent side effects** are **infusion reactions** (see below for information on how often patients experience these), which can happen at the time of the infusion or within 24 hours after the infusion. In most cases these are mild but some serious reactions are possible. Occasionally allergic reactions could occur.

To try to reduce infusion reactions, your doctor will give you medicine (corticosteroids) before each of the first 3 infusions of a LEMTRADA course. Other treatments to limit these reactions can also be given before the infusion or when you experience symptoms. In addition, you will be monitored during the infusion and for 2 hours after the infusion has been completed. In case of serious reactions, the infusion may be slowed down or even stopped.

Please refer to the **LEMTRADA Patient Guide** for more information about these events.

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
- Decrease in white blood cell numbers (lymphocytes, leukocytes, neutrophils)
- 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, herpes zoster infection, tooth infection
- 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
- exaggerated immune response
- 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, migraine
- feelings of anxiety, depression
- abnormally heavy, prolonged or irregular menstruation
- acne, redness of the skin, excessive sweating, skin discoloration, skin lesion, dermatitis
- nose bleeds, bruises
- hair loss
- asthma
- muscular and bone pain, chest discomfort

**Uncommon** (may affect up to 1 in 100 people)
- **Infections**: stomach flu, inflammation of the gums, nail fungus, tonsil inflammation, acute sinusitis, bacterial skin infection, cytomegalovirus infection
- pneumonitis
- athlete's foot
- abnormal vaginal smear
- increased sensation, sensory disturbance such as numbness, tingling and pain, tension headache
- double vision
- pain in ear
- difficulty swallowing, throat irritation, productive cough
- decreased weight, weight increase, red blood cell decrease, blood glucose increase, increase in red blood cell size
- constipation, acid reflex, dry mouth
- rectal bleeding
- bleeding of gums
- decreased appetite
- blisters, night sweats, face swelling, eczema
- stiffness, arms or legs discomfort
- kidney stones, excretion of ketone bodies in urine, kidney disease
- decreased/weak immune system
- tuberculosis
- inflammation of the gallbladder with or without gallstones
- warts
- autoimmune disorder characterized by bleeding (acquired haemophilia A)
- Sarcoidosis
- autoimmune brain disorder (autoimmune encephalitis)
- patches of skin that have lost colour (Vitiligo)
- autoimmune patchy hair loss (alopecia areata)

**Rare** (may affect up to 1 in 1000 people)
- excessive activation of white blood cells associated with inflammation (haemophagocytic lymphohistiocytosis)
- autoimmune blood clotting disorder (thrombotic thrombocytopenic purpura, TTP)

**Not known** (frequency cannot be estimated from the available data):
- listeriosis/listeria meningitis
- bleeding in lungs
- heart attack
- stroke
- tears in carotid or vertebral arteries (blood vessels supplying the brain)
- infection due to a virus known as Epstein-Barr virus
- inflammatory condition that affects multiple organs, Adult Onset Still's Disease (AOSD)

Show the Patient Alert Card and this package leaflet to any doctor involved with your treatment, not only to your neurologist.

You will also find this information in the Patient Alert Card and Patient Guide that you have been given by your doctor.

**Reporting of side effects**
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of medicine

## 5. How to store LEMTRADA

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the outer carton and the vial label after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C-8°C).

Do not freeze.

Store in the original package to protect from light.

It is recommended that the product is used immediately after dilution, due to a possible risk for microbial contamination. If it is not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and should not be longer than 8 hours at 2°C to 8°C, under protection from light.

## 6. Contents of the pack and other information

**What LEMTRADA contains**
The **active substance** is alemtuzumab.
Each vial contains 12 mg alemtuzumab in 1.2 ml.

The **other ingredients** are:
- disodium phosphate dihydrate (E339)
- disodium edetate dihydrate
- potassium chloride (E508)
- potassium dihydrogen phosphate (E340)
- polysorbate 80 (E433)
- sodium chloride
- water for injections

**What LEMTRADA looks like and contents of the pack**
LEMTRADA is a clear, colourless to slightly yellow concentrate for solution for infusion (sterile concentrate) that comes in a glass vial with stopper.

There is 1 vial in each carton.

**Marketing Authorisation Holder**
Sanofi
410 Thames Valley Park Drive
Reading
Berkshire
RG6 1PT
UK
Tel: 0800 035 2525
Email: uk-medicalinformation@sanofi.com

**Manufacturer**
EUROAPI UK Limited
37 Hollands Road
Haverhill
Suffolk CB9 8PU
United Kingdom

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor.

**This leaflet was last revised in November 2023**

**Other sources of information**

To assist in the education of patients regarding potential side-effects and instructions on what to do in case of certain side-effects, the following risk minimisation materials are available:

| | |
|---|---|
| 1 Patient Alert Card: | For the patient to present to other healthcare providers to alert them to the use of LEMTRADA in this patient. |
| 2 Patient Guide: | For further information on autoimmune reactions, infections and other information. |

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- Complete baseline tests and screening as described in SmPC section 4.
- The vial contents should be inspected for particulate matter and discolouration prior to administration. Do not use if particulate matter is present or the concentrate is discoloured. DO NOT SHAKE VIALS PRIOR TO USE.
- Use aseptic techniques to withdraw 1.2 ml of LEMTRADA from the vial and inject into 100 ml of sodium chloride 9 mg/ml (0.9%) solution for infusion or glucose (5%) solution for infusion. The bag should be inverted gently to mix the solution. Care should be taken to ensure the sterility of the prepared solution.
- Administer LEMTRADA infusion solution via intravenous administration over approximately 4 hours.
- Other medicinal products should not be added to the LEMTRADA infusion solution or simultaneously infused though the same intravenous line.
- It is recommended that the product is used immediately after dilution, due to a possible risk for microbial contamination. If it is not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and should not be longer than 8 hours at 2°C to 8°C, under protection from light.
- Procedures for proper handling and disposal should be observed. Any spillage or waste material should be disposed of in accordance with local requirements.

  After each infusion, the patient should be observed for 2 hours for infusion associated reactions. Symptomatic treatment can be initiated if needed – see SmPC. Continue to test the patient every month for autoimmune conditions, until 4 years after last infusion. See LEMTRADA Health Care Professional Guide for more information, or read the summary of product characteristics.