

**LEMTRADA**<sup>®</sup>  
alemtuzumab<sup>12mg</sup>

## Patient Guide Risk Minimisation Information for Patients

Important safety information  
for patients starting therapy  
with Lemtrada

If you notice any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the patient information leaflet. You can also report side effects directly to:

In Ireland by contacting: HPRa Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2, Tel: 01 6764971, Fax: 01 6767836, Website: [www.hpra.ie](http://www.hpra.ie), email: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

In the UK: It is easiest and quickest to report side effects online via the Yellow Card website <https://yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store.

Alternatively, prepaid Yellow Cards for reporting are available by writing to FREEPOST YELLOW CARD (no other address details necessary), by emailing [yellowcard@mhra.gov.uk](mailto:yellowcard@mhra.gov.uk), at the back of the British National Formulary (BNF), by telephoning the Commission on Human Medicines (CHM) free phone line: 0800 731 6789, or by downloading and printing a form from the Yellow Card section of the MHRA website.

By reporting side effects you can help provide more information on the safety of this medicine.

Side effects should also be reported to Sanofi:

UK: Tel: 0800 0902314. Email: [UK-drugsafety@sanofi.com](mailto:UK-drugsafety@sanofi.com)

IE: Tel: 01 403 5600. Email: [IEPharmacovigilance@sanofi.com](mailto:IEPharmacovigilance@sanofi.com)

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# Welcome

**Your doctor has given you this Patient Guide and a Patient Alert Card to inform you about your current treatment with Lemtrada. This Patient Guide is to be carefully reviewed with your doctor when you are first prescribed Lemtrada and on a regular basis at follow-up visits.**

This Patient Guide is to make you aware of symptoms of autoimmune disorders (these are conditions in which your immune system mistakenly attacks your body) and serious infections as well as the need to be compliant with testing and be vigilant for symptoms and to seek immediate medical attention should these occur. There is also a section to keep track of all of the doctors you may be seeing for your healthcare. This includes the doctor treating your multiple sclerosis (MS) and any other doctor you see on a regular basis.

The Patient Alert Card is to inform any healthcare professional about your Lemtrada treatment. **You must carry the Patient Alert Card with you at all times and show it to any healthcare professional.**

In addition, if your nurse or doctor has not given you the Patient Information Leaflet, please ask for it. Alternatively this document can be found listed when searching a specific product on the Electronic Medicines Compendium (eMC) website: [www.medicines.org.uk/emc](http://www.medicines.org.uk/emc) in the UK and the medicines.ie website: [www.medicines.ie](http://www.medicines.ie) in Ireland

The Patient Guide and the Patient Alert Card are available electronically on the Electronic Medicines Compendium (eMC) website: [www.medicines.org.uk/emc](http://www.medicines.org.uk/emc) in the UK and the HPRRA website: [www.hpra.ie/homepage/medicines/safety-information/educational-material](http://www.hpra.ie/homepage/medicines/safety-information/educational-material) in Ireland.

These materials are also available upon request from the Sanofi Medical Information Department:

UK: Telephone: 0845 372 7101; Email: [UK-medicalinformation@sanofi.com](mailto:UK-medicalinformation@sanofi.com)

Ireland: Telephone: 01 403 5600; Email: [IEmedinfo@sanofi.com](mailto:IEmedinfo@sanofi.com)

**This guide is not intended to take the place of discussions with your doctor or other healthcare professionals who are treating your MS. It should also be read along with the Patient Information Leaflet for Lemtrada. Be sure to tell your doctor or healthcare professional if you notice any of the signs or symptoms described in this guide.**

# 1. Introduction to Lemtrada

## What is Lemtrada?

Lemtrada is a prescription medicine used to treat relapsing remitting multiple sclerosis (MS) in adults. Lemtrada does not cure MS but it can decrease the number of MS relapses. It can also help to slow down signs and symptoms of MS.

Lemtrada adjusts your immune system to limit its attacks on your nervous system. After having 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.

## 2. Overview of Lemtrada treatment

### How is Lemtrada given?

Lemtrada is given to you by infusion, using a needle through which it will be delivered into your blood stream. Lemtrada is given in at least two courses of treatment. You will receive the first course for a few hours per day for 5 days in a row. Then, one year later, you will receive the next course for 3 days in a row. Lemtrada is not like some other drugs that you have to take regularly (for example, once a day) to have an effect. Some patients, if they have symptoms or signs of MS disease after the initial two courses, may receive one or two additional treatment courses. An additional treatment course will consist of one infusion per day for 3 days administered at least a year after the prior treatment.

You will need to be monitored for side effects for 4 years after your last infusion of Lemtrada (see **'Will I need to have any tests done after treatment with Lemtrada?' on page 4**)

### Do I need to do anything BEFORE I will be treated with Lemtrada?

To make sure Lemtrada is the right therapy for you, your doctor needs some information. Therefore, you need to inform your doctor about:

- All medicines that you are taking
- If you are suffering from any infection
- If you have been diagnosed with cancer
- If you have been diagnosed with abnormalities of the cervix
- If you are pregnant or plan to become pregnant very soon

Your doctor will check the vaccinations that you have had and may advise you to complete the standard vaccination programme if you have not done so. Your doctor may also advise additional vaccinations to be done before you start treatment with Lemtrada.

If you live in an area where tuberculosis is often seen, your doctor will arrange screening.

Your doctor will also discuss your diet. Listeriosis/Listeria meningitis has been reported in Lemtrada treated patients, generally within one month of Lemtrada infusion. To reduce the risk of infection, patients receiving Lemtrada should avoid ingestion of uncooked or undercooked meats, soft cheeses and unpasteurised

## 2. Overview of Lemtrada treatment

dairy products two weeks prior to, during, and for at least one month after Lemtrada infusion. It is vitally important to follow these dietary restrictions for the full 6 weeks advised. Your doctor may also provide you with additional guidelines or advice on dietary requirements, before, during and after infusion with Lemtrada. As a precaution you may be prescribed antibiotics to prevent an infection, this is not a requirement but any medication prescribed by your doctor should be taken as directed.

Your doctor will perform blood and urine tests before you start treatment with Lemtrada. These tests are done to see whether you are suitable to be treated with Lemtrada.

### **Will I need to have any tests done AFTER treatment with Lemtrada?**

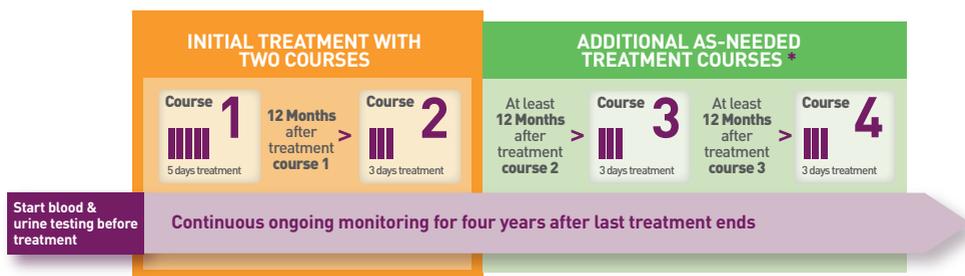
Treatment with Lemtrada may increase the risk of autoimmune conditions (conditions in which your immune system mistakenly attacks your body). These may occur even many years after your treatment (described in Section 3 of this guide). Therefore you will have to be monitored monthly by having your blood and urine tested for several years. Your doctor will check the results of these tests to see if you have developed any side effect(s).

It is very important that you continue to have these checks for 4 years/48 months after your last course of treatment with Lemtrada, even if you are feeling well (this means that you have no noticeable symptoms or side effects) and your MS symptoms are under control. Side effects may occur even many years after your last course of treatment with Lemtrada. In rare cases, they can be life-threatening, so it is very important that you continue to be checked, and that you watch out for symptoms. By doing so, it will be most likely that a problem will be detected early and treatment can start right away.

This means that you need to commit to the monthly blood and urine tests, continuing for 4 years after your last course of treatment with Lemtrada. You and your doctor will work together as a team to make sure you get these tests done, and to plan them around your normal activities. If you are a woman, it is also important to avoid urine testing during your menstrual periods as this may give a false result.

To help you better understand the duration of the effects of treatment and the length of required follow-up, Figure 1 shows this process.

**Figure 1 - Duration of the effects of treatment and the length of required follow-up**



**\*NOTE** A study following patients for 6 years after first infusion (course 1) has shown that a majority of patients do not need further treatment after the 2 initial treatment courses.

The following table shows you which tests are done, when, and for how long.

**Table 1 - Type and timing of tests**

Test	When	For how long?
Blood test	Before treatment starts and every month after treatment	For 4 years after your last Lemtrada infusion
Urine test	Before treatment starts and every month after treatment	For 4 years after your last Lemtrada infusion

## 3. Side effects

In the following sections, you will learn more about serious infections and autoimmune conditions which are some of the side effects of Lemtrada, including the signs and symptoms that you may experience and what to do if they happen.

### Serious infections

Patients treated with Lemtrada are at a higher risk for getting a serious infection. If you develop symptoms of serious infection such as fever, chills, and/or swollen glands, you may have to go to hospital for treatment.

You should also 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.

It's important to tell the doctors in the hospital that you have received treatment with Lemtrada.

Tell your doctor if you are suffering from a serious infection before the initiation of your Lemtrada treatment, your doctor should delay the treatment until the infection is resolved.

**You must not be vaccinated with certain types of vaccines (live viral vaccines) if you have recently received treatment with Lemtrada.**

### Autoimmune conditions

As mentioned above, patients receiving Lemtrada are at risk of serious infections and certain autoimmune conditions. These side effects can occur weeks, months or years after treatment with Lemtrada (delayed side effects).

**The autoimmune conditions include:**

- Thyroid disorders
- A condition called Immune Thrombocytopenic Purpura (ITP) (described in the next section)
- Certain types of kidney diseases

The cause of these side effects is not clear. However, it is known that you are at higher risk for these events if you have received Lemtrada.

**All of these conditions can be treated when identified early, but delaying treatment increases the risk of complications. This is why it is so important to recognise and immediately report any signs or symptoms of these conditions to your doctor.**

## 1. Thyroid disorders

The thyroid is a gland in the lower part of the neck. The thyroid produces hormones that are important throughout your body. In some people, the immune system may mistakenly attack the cells of the thyroid gland (autoimmune thyroid condition). This affects its ability to make and control the level of hormones.

**Lemtrada very commonly causes development of thyroid disorders including:**

- > **Overactive thyroid gland (also called hyperthyroidism):** the thyroid produces too much hormone.
- > **Underactive thyroid gland (also called hypothyroidism):** the thyroid does not produce enough hormone.

Your blood will be checked before you start your treatment with Lemtrada and every 3 months after your initial treatment course until 4 years after your last infusion. This blood test will help your doctor detect any thyroid disorders early.

### **What are the signs and symptoms of an overactive thyroid?**

Symptoms may include:

- > Excessive sweating
- > Unexplained weight loss
- > Eye swelling
- > Nervousness
- > Fast heartbeat

# 3. Side effects

## What are the signs and symptoms of an underactive thyroid?

Symptoms may include:

- > Unexplained weight gain
- > Feeling cold
- > Worsening tiredness
- > Newly occurring constipation

## What if I develop a thyroid disorder?

Tell your doctor if you experience any of these symptoms.

Depending on the type of thyroid disorder you are experiencing, your doctor will decide which treatment is best for you. It is very important that you follow your doctor's recommendations to be sure that you will benefit most from your treatment. Sometimes you do not need medication. However in some cases, you will have to take medication for the rest of your life for your thyroid disorder. In some situations the thyroid may need to be removed.

If you develop a thyroid disorder, it is very important that you are properly treated for it, especially if you are female and become pregnant after using Lemtrada. Having an untreated thyroid disorder could harm your baby before it is born or after birth.

## 2. Immune Thrombocytopenic Purpura (ITP; a bleeding disorder)

ITP is a condition which results in a decrease in the number of platelets in the blood. ITP is common and may affect up to 1 in 10 people. Platelets are necessary for normal blood clotting. ITP can cause severe bleeding. If detected promptly, it is treatable, but if left untreated it may lead to serious health problems and possibly death. A blood test will help your doctor watch for changes in your platelet count, in order to catch this side effect early. Therefore, your doctor will have your blood tested before starting Lemtrada, and on a monthly basis after your initial treatment course. The monthly testing must continue for 4 years after your last treatment course.

Importantly, **ITP can start quickly and may occur in between the blood tests.** It is therefore important that you are aware of the signs and symptoms.

## What are the signs and symptoms of ITP?

- > Small scattered spots on your skin that are red, pink or purple
- > Easy bruising
- > Bleeding from a cut that is harder to stop than usual
- > Heavier, longer or more frequent menstrual periods than normal
- > Bleeding between your menstrual periods
- > Bleeding from your gums or nose that is new or takes longer than usual to stop
- > Coughing up blood

Take a look at Figure 2 which shows examples of bruises and rashes caused by ITP.

**Call your doctor immediately if you have any of these signs or symptoms. If you cannot reach your doctor, seek immediate medical attention (e.g. at A&E department of the hospital) and show them your Lemtrada patient card.**

## What if I develop ITP?

It is best to identify and treat ITP **as early as possible**. That is why it is so important that you continue to have your monthly blood test, which could detect a problem before you notice any symptoms. It is also important that you, your family members and/or caregivers are watching for any of the signs or symptoms described in this guide. Delaying treatment of ITP raises the chance of more serious problems.

# 3. Side effects

Figure 2 – Examples of bruises and rashes caused by ITP



NOTE: These pictures are only a guide to show examples of bruises or rashes

- 1** Example of a leg with easy or excessive bruising.  
**Where on the body?** It is important to note bruises could occur anywhere on your body, not just on your legs.
- 2** Example of legs with scattered spots under the skin that are red, pink or purple. They might look like pin pricks (petechia) or they can be a little bigger (purpura).  
**Where on the body?** It is important to note that the spots could occur anywhere on your body, not just on your legs.
- 3** Example of spots due to bleeding under the tongue.  
**Where on the body?** This could also occur anywhere in your mouth - under the tongue, on the roof of your mouth, on your inner cheeks, on your tongue or on your gums.

If detected early, ITP is usually treatable. If you develop ITP, you and your doctor will decide which treatment is best for you.

**If you notice any of the signs or symptoms (as described above), call your doctor right away to report the symptoms. If you cannot reach your doctor seek immediate medical attention (e.g. at A&E department of the hospital). Show them your Lemtrada patient card.**

## 3. Kidney disorders (anti-Glomerular Basement Membrane disease)

Rarely Lemtrada causes kidney problems, such as a condition known as anti-Glomerular Basement Membrane or anti-GBM disease. Anti-GBM disease is an autoimmune condition that can result in severe damage to the kidneys.

Damage to the lungs may also occur with anti-GBM disease, although this was not seen in studies with Lemtrada. If not treated, it can cause kidney failure requiring chronic dialysis or transplantation, and may eventually lead to death.

A blood test and urine test will help your doctor watch for signs of kidney disease to catch this side effect early. Your doctor will have your blood and urine tested before starting Lemtrada, and on a monthly basis after your initial treatment course. If you are a woman, it is also important to avoid urine testing during your menstrual period as this may give a false result. This testing will continue for 4 years after your last infusion. Importantly, anti-GBM disease can also be detected by certain signs and symptoms that you need to be aware of.

### **What are the signs and symptoms of kidney problems, such as anti-GBM disease?**

- > **Blood in the urine:** your urine may be red or tea-colored
- > **Swelling:** in your legs or feet
- > **Coughing up blood:** you may cough up blood

**Anti-GBM disease could potentially also damage your lungs, which can result in coughing up blood.**

### **What if I develop kidney problems?**

Most of the time, doctors can treat kidney problems. It is best to begin treatment as early as possible. It is important that you are familiar with the signs and symptoms of kidney problems and anti-GBM disease, and complete your regular laboratory tests (blood tests and urine tests). Kidney problems will almost always need treatment. Treatment can begin right away, if needed.

**If you notice any of the signs or symptoms (as described above), call your doctor right away to report the symptoms. If you cannot reach your doctor seek immediate medical attention.**



### **IMPORTANT**

**Since all of these autoimmune conditions could occur soon but also long after you received a course of treatment with Lemtrada, it is very important that you continue to have your monthly tests (even if you are feeling well).**

**You must also continue to watch for signs and symptoms:**

- **Do this for 4 years after your last course of treatment with Lemtrada**
- **Early detection and diagnosis may give you the best opportunity for improvement**
- **Carry your Patient Alert Card with you and show it to any health care providers who are providing you treatment (including for non-MS conditions) and especially in the event of a medical emergency**

# 4. Other helpful information

## What do I need to know about vaccination?

Before receiving each course of your treatment with Lemtrada, your doctor will check that you are up to date with your vaccinations. If you need a vaccination, you will have to wait for 6 weeks after vaccination to have your Lemtrada treatment. Tell your doctor if you have already had a vaccination within the last 6 weeks.

## Fertility/Pregnancy/Contraception

It is not known if Lemtrada will have an effect on fertility during the time when it is in your system. Talk to your doctor if you are thinking about trying to become pregnant.

It is not known if Lemtrada could harm an unborn child. You should use effective contraceptives when you receive your course of treatment with Lemtrada and for 4 months following each course of treatment with Lemtrada (unless your doctor tells you it is not needed since you are unable to have a child, for example if you have had a hysterectomy). This is to ensure there is no Lemtrada left in your body before you conceive a child. You should be sure to discuss with your doctor if you are planning to become pregnant.

If you are already pregnant, you and your doctor will need to decide whether the benefit of you receiving treatment outweighs the potential risk to your unborn baby.

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 breastfeed 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 breastfeed your baby. He/she will advise you what is right for you and your baby.

## What other information should I tell my doctor?

Be sure to tell your doctor or healthcare team about any new health problems you have developed and any new medicines you have taken since your last appointment. Those medicines may include prescription and non-prescription medicines, vitamins, and herbal supplements. It is important for your doctor to know this and to manage your treatments.

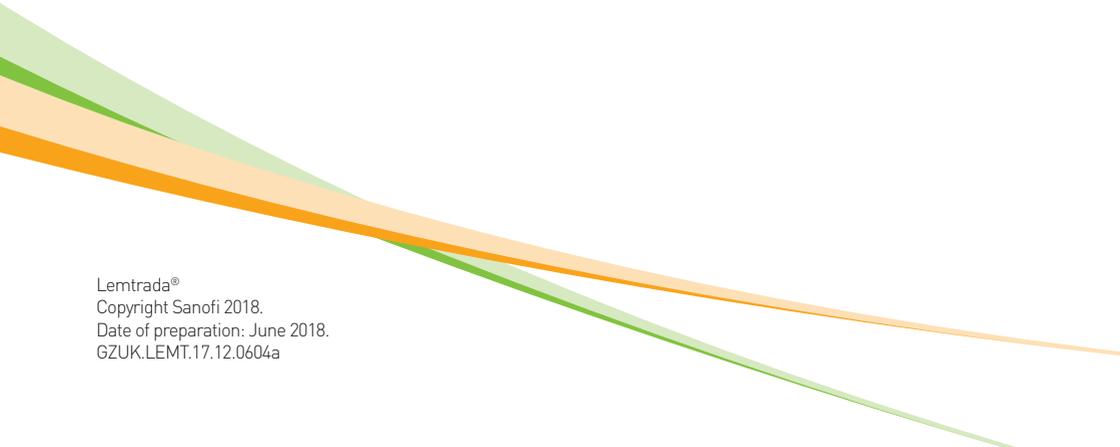
# 5. Planning your monitoring schedule

The autoimmune conditions described in this guide could occur long after you received a course of treatment with Lemtrada. It is very important that you continue to have your monthly tests (even if you are feeling well) for 4 years after your last treatment course.

# 6. How to reach your doctors

To make it easier to contact your doctor(s) or healthcare team, please fill in their telephone numbers and addresses in the chart below.

Doctor/Healthcare Team	Telephone Number	Address



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