Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) – 1986

The medicine is dispensed according to a physician's prescription only

Lamogine 25 mg, 50 mg, 100 mg, 200 mg tablets

Each tablet contains: 25 mg, 50 mg, 100 mg, 200 mg lamotrigine.

Inactive ingredients and allergens in this medicine: See section 6 'Additional information' and section 2 under 'Important information about some of this medicine's ingredients'.

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, refer to the physician or the pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. What is the medicine intended for?

Lamogine is intended for the treatment of epilepsy

In adults and adolescents aged 13 years and above:

- Lamogine is given as monotherapy or in combination with other medicines to treat partial seizures and generalized seizures, including tonic-clonic seizures.
- Seizures that occur with Lennox-Gastaut syndrome. Lamogine is given as combination therapy with other medicines but may be used as the initial antiepileptic medicine when starting treatment of Lennox-Gastaut syndrome.

In children and adolescents aged 2 to 12 years:

- Lamogine is given as combination therapy with other medicines to treat partial seizures and generalized seizures, including tonic-clonic seizures and seizures occurring with Lennox-Gastaut syndrome.
- Lamogine is given as monotherapy in typical absence seizures.

Lamogine is intended for treatment of bipolar disorder

In adults aged 18 years and above:

- Lamogine is given to prevent depressive episodes in patients with bipolar disorder who experience predominantly depressive episodes.

Lamogine is not intended for immediate (acute) treatment of manic or depressive episodes.

Therapeutic group:

Lamogine belongs to a group of medicines called anticonvulsants. Lamogine blocks signals in the brain that trigger epileptic seizures.

2. Before using the medicine

Do not use this medicine if:

- **you are sensitive** (allergic) to the active ingredient lamotrigine or to any of the other ingredients in this medicine (listed in section 6).

If this applies to you, **tell your physician** and don't take Lamogine.

Special warnings regarding the use of the medicine

Tell your physician before starting treatment with Lamogine if:

- **you have any kidney problems**
- **you have ever developed a rash** after taking lamotrigine or other medicines for bipolar disorder or epilepsy
- **you get a rash or sunburn after taking lamotrigine and having been exposed to sunlight or artificial light (as in a solarium).** Your physician will check your treatment and may advise you to avoid sunlight or protect yourself against the sun (for example by using sunscreen and/or wearing protective clothing)
- **you have ever developed meningitis after taking lamotrigine** *(read the description of these symptoms in section 4 of this leaflet: 'Rare side effects')*
- **you are already taking medicine that contains lamotrigine**
- **you have a condition called Brugada syndrome or other heart problems.** Brugada syndrome is a genetic disease that causes abnormal electrical activity in the heart. Lamogine may cause ECG abnormalities, which may lead to arrhythmias (abnormal heart rhythm).

If any of these applies to you: **Tell your physician,** who may decide to lower the dosage or that Lamogine is not suitable for you.

Important information about potentially life-threatening reactions

A small number of people taking lamotrigine get an allergic reaction or potentially life-threatening skin reaction, which may develop into more serious problems if they are not treated. These can include Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). You need to know the symptoms to look out for while you are taking Lamogine. This risk may be associated with a variant in genes in people from Asian origin (mainly Han Chinese and Thai). If you are of such origin and have been tested before to see if you carry this genetic variant (HLA-B* 1502), discuss this with your physician before taking Lamogine.

Read the description of these symptoms in section 4 of this leaflet under 'Potentially life-threatening reactions: get medical help straight away'.

Haemophagocytic lymphohistiocytosis (HLH)

There have been reports of a rare but very serious immune system reaction in patients taking lamotrigine.

Contact your physician or pharmacist immediately, if you experience any of the following symptoms while taking Lamogine: fever, rash, neurological symptoms (e.g., tremor, confusion, disturbances of brain function).

Thoughts of harming yourself or suicide

Anti-epileptic medicines are used to treat several conditions, including epilepsy and bipolar disorder. People with bipolar disorder can sometimes have suicidal thoughts or thoughts of harming themselves. If you have bipolar disorder, you may be more likely to think like this:

- when you first start treatment or with a change in dosage
- if you previously had thoughts about harming yourself or about suicide
- if you are under 25 years old

If you have distressing thoughts or experiences, or if you notice that you feel worse or develop new symptoms while you're taking Lamogine:

Refer to a physician as soon as possible or go to the nearest hospital for help.

You may find it helpful to tell a family member, caregiver, or a close friend that you can become depressed or have significant mood swings and ask them to read this leaflet. You can ask them to tell you if they are concerned about your depression or about other changes in your behaviour.

A small number of people being treated with antiepileptics such as Lamogine have also had thoughts of harming or killing themselves. If at any time you have these thoughts, **immediately contact your physician.**

If you're taking Lamogine for epilepsy

The seizures in some types of epilepsy may occasionally become worse or happen more often while you're taking Lamogine. Some patients may experience severe seizures, which may cause serious health problems. If your seizures happen more often or if you experience a severe seizure while you're taking Lamogine:

Refer to a physician as soon as possible.

Children and adolescents

Lamogine is not intended for children under 2 years of age.

Lamogine is not intended for people aged under 18 years to treat bipolar disorder. Medicines to treat depression and other mental health problems increase the risk of suicidal thoughts and behaviour in children and adolescents aged under 18 years.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and food supplements, tell the physician or the pharmacist. Your physician needs to know if you are taking other medicines to treat epilepsy or mental health problems. This is to make sure you take the correct dosage of Lamogine. These medicines include:

- **oxcarbazepine, felbamate, gabapentin, levetiracetam, pregabalin, topiramate** or **zonisamide,** used to treat **epilepsy**
- **lithium, olanzapine** or **aripiprazole,** used to treat **mental health problems**
- **bupropion,** used to treat **mental health problems** or to **stop smoking**
- **paracetamol,** used to treat **pain and fever**

Tell your physician if you are taking any of these.

Some medicines interact with Lamogine or make it more likely that people will have side effects. These include:

- **valproate,** used to treat **epilepsy** and **mental health problems**
- **carbamazepine,** used to treat **epilepsy** and **mental health problems**
- **phenytoin, primidone** or **phenobarbitone,** used to treat **epilepsy**
- **risperidone,** used to treat **mental health problems**
- **rifampicin,** which is an **antibiotic**
- **medicines** used to treat **Human Immunodeficiency Virus (HIV) infection** (a combination of lopinavir and ritonavir or atazanavir and ritonavir)
- **hormonal contraceptives,** such as **contraceptive pills** (see below)

Tell your physician if you are taking, or if you start or stop taking any of these.

Hormonal contraceptives (such as contraceptive pills) can affect the way Lamogine works.

Your physician may recommend that you use a particular type of hormonal contraceptive or another method of contraception such as condoms, a cap, or coil. If you are using a hormonal contraceptive like contraceptive pills, your physician may take samples of your blood to check the level of lamotrigine. If you are using a hormonal contraceptive or if you plan to start using one:

Talk to your physician, who will discuss suitable methods of contraception with you.

Lamogine can also affect the way hormonal contraceptives work, although it's unlikely to make them less effective. If you are using a hormonal contraceptive and you notice any changes in your menstrual pattern, such as breakthrough bleeding or spotting between periods, **tell your physician.** These may be signs that Lamogine is affecting the way your contraceptive is working.

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your physician or pharmacist for advice before taking this medicine.

- **You should not stop treatment without discussing this with your physician.** This is particularly important if you have epilepsy.
- Pregnancy may alter the effectiveness of Lamogine, so you may need blood tests and your dose of Lamogine may be adjusted.
- There may be a small increased risk of birth defects, including a cleft lip or cleft palate, if Lamogine is taken during the first 3 months of pregnancy.
- Your physician may advise you to take extra folic acid if you're planning to become pregnant and while you're pregnant.

If you are breast-feeding, or are planning to breast-feed, ask your physician or pharmacist for advice before taking this medicine. The active ingredient of Lamogine passes into breast milk and may affect your baby. If you decide to breast-feed, your physician will discuss the risks and benefits of breast-feeding while you're taking Lamogine and will check your baby from time to time to see whether drowsiness, rash or poor weight gain occur. Inform your physician if you notice any of these symptoms in your baby.

Driving and using machines

Lamogine can cause dizziness and double vision.

Don't drive or use machines unless you are sure you're not affected.

Children should be warned against riding bicycles or playing near roads, etc.

If you have epilepsy, talk to your physician about driving and using machines.

Important information about some of the ingredients in this medicine

Lamogine tablets contain lactose. If you have been told by your physician that you have an intolerance to some sugars, consult your physician before taking this medicine.

Lamogine tablets contain less than 1 mmol sodium (23 mg) per tablet, i.e., they are essentially sodium-free.

3. How should you use the medicine?

Always use this medicine according to the physician's instructions. You should check with the physician or the pharmacist if you are not sure about your dose or about how to take this medicine.

The dosage and treatment will be determined only by the attending physician on an individual basis according to the severity of the disease.

How much Lamogine to take

It may take a while to find the best dosage of Lamogine for you. The dosage you take will depend on:

- your age
- whether you are taking Lamogine with other medicines
- whether you have any kidney or liver problems

Your physician will prescribe you with a low dosage to start and will gradually increase the dosage over a few weeks until you reach a dosage that works for you (called the effective dosage). **Never take more Lamogine than your physician tells you to.**

Do not exceed the recommended dose.

How to take your dose of Lamogine

Take your dose of Lamogine once or twice a day, as your physician instructed you. It can be taken with or without food.

Always take the full dose that your physician has prescribed for you.

Your physician may also advise you to start or stop taking other medicines, depending on what condition you're being treated for and the way you respond to treatment.

Lamogine tablets can be swallowed whole with a little water.

For children and those who have difficulty swallowing tablets: the tablet can be placed in spoonful of water and swallowed after a few minutes, when the tablet has completely disintegrated.

Lamogine 25 mg – As there is no score line, do not split. There is no information about crushing/chewing.

Lamogine 50 mg, 100 mg, 200 mg – You may split. There is no information about crushing/chewing.

If you have accidently taken a higher dosage

If you have taken an overdose or if a child has accidentally swallowed the medicine, **refer immediately to a physician or to the hospital emergency room** and bring the package of the medicine with you.

If you take too much **Lamogine, you are more likely to have serious side effects which could be fatal.**

Someone who has taken too much Lamogine may have any of these symptoms:

- rapid, uncontrollable eye movements (nystagmus)
- clumsiness and lack of coordination, affecting balance (ataxia)
- heart rhythm changes (usually detected on ECG)
- loss of consciousness, fits (seizures) or coma

If you forgot to take a single dose of Lamogine

Don't take extra tablets to make up for a forgotten dose. Take your next dose at the usual time.

If you forgot to take several doses of Lamogine

Ask your physician for advice on how to start taking it again. It is important that you do this.

Adhere to the treatment as recommended by your physician.

Even if your health improves, do not stop taking this medicine without first consulting your physician.

Don't stop taking Lamogine without advice

You must take Lamogine for as long as your physician recommends. Don't stop unless your physician advises you to.

If you're taking Lamogine for epilepsy

To stop taking Lamogine, **it is important that the dosage is reduced gradually,** over about 2 weeks. If you suddenly stop taking Lamogine, your epilepsy may come back or get worse.

If you're taking Lamogine for bipolar disorder

Lamogine may take some time to work, so you are unlikely to feel better straight away. If you stop taking Lamogine, your dosage will not need to be reduced gradually but you should still talk to your physician first, if you want to stop taking Lamogine.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have any other questions regarding the use of the medicine, consult the physician or the pharmacist.

4. Side effects

As with any medicine, use of Lamogine may cause side effects in some of the users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

Potentially life-threatening reactions: get medical help straight away

A small number of people taking lamotrigine develop an allergic reaction or potentially life-threatening skin reaction, which may develop into more serious problems if they are not treated.

These symptoms are more likely to happen during the first few months of treatment with Lamogine, especially if the starting dosage is too high or if the dosage is increased too quickly or if Lamogine is taken with another medicine called *valproate*. Some of the symptoms are more common in children, so parents should be especially careful to watch out for them.

Symptoms of these reactions include:

- **skin rashes or redness,** which may develop into serious or sometimes life-threatening skin reactions including rash with target-shaped lesions (erythema multiforme), widespread rash with blisters and peeling skin, particularly occurring around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome), extensive peeling of the skin (more than 30% of the body surface - toxic epidermal necrolysis) or extended rashes with liver, blood and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as hypersensitivity syndrome - DRESS)
- **ulcers in the mouth, throat, nose or genitals**
- **a sore mouth or red or swollen eyes** (conjunctivitis)
- **a high temperature (fever),** flu-like symptoms or drowsiness
- **swelling around your face** or **swollen glands** in your neck, armpit or groin
- **unexpected bruising or bleeding,** or the fingers turning blue
- **a sore throat** or more infections (such as colds) than usual
- increased levels of liver enzymes seen in blood tests
- an increase in a type of white blood cell (eosinophils)
- enlarged lymph nodes
- involvement of the organs of the body including liver and kidneys

In many cases, these symptoms will be signs of less serious side effects, **but you must be aware that they are potentially life-threatening and can develop into more serious problems,** such as organ failure, if they are not treated. If you notice any of these symptoms:

Refer to a physician immediately. Your physician may decide to carry out tests on your liver and kidneys or your blood and may tell you to stop taking Lamogine. In case you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis, your physician will tell you that you must never take Lamogine again.

Haemophagocytic lymphohistiocytosis (HLH) (see in section 2: 'Special warnings regarding the use of the medicine').

Very common side effects

Effects that may occur **in more than 1 in 10** users:

- headache • skin rash

Common side effects

Effects that may occur **in up to 1 in 10** users:

- aggression or irritability • feeling sleepy or drowsy • feeling dizzy • tremors • insomnia • feeling agitated • diarrhoea • dry mouth • nausea or vomiting • feeling tired • pain in the back or joints, or elsewhere

Uncommon side effects

Effects that may occur **in up to 1 in 100** users:

- clumsiness and lack of coordination (ataxia)
- double vision or blurred vision
- unusual hair loss or thinning (alopecia)
- skin rash or sunburn after exposure to sunlight or artificial light (photosensitivity)

Rare side effects

Effects that may occur **in up to 1 in 1,000** users:

- skin reaction that causes red spots or lesions on the skin, that may look like a target or "bulls-eye" with a dark red centre surrounded by paler red rings (erythema multiforme).
- a life-threatening skin reaction (Stevens-Johnson syndrome) (see also the information at the beginning of section 4)
- a group of symptoms that appear together including: fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light. This may be caused by an inflammation of the membranes that cover the brain and spinal cord (meningitis). These symptoms usually disappear once treatment is stopped; however, if the symptoms continue or get worse, **contact your physician**
- rapid, uncontrollable eye movements (nystagmus)
- itchy eyes, with discharge and crusting of it on the eyelids (conjunctivitis)

Very rare side effects

Effects that may occur **in up to 1 in 10,000** users:

- a life-threatening skin reaction (toxic epidermal necrolysis) (see also the information at the beginning of section 4)
- drug reaction with Eosinophilia and Systemic Symptoms (DRESS) (see also the information at the beginning of section 4)
- a high temperature (fever) (see also the information at the beginning of section 4)
- swelling around the face (oedema) or swollen glands in the neck, armpit or groin (enlarged lymph nodes) (see also the information at the beginning of section 4)
- changes in liver function, which will show up in blood tests or liver failure and yellowing of the skin (see also the information at the beginning of section 4)
- a serious blood clotting disorder, which can cause unexpected bleeding or bruising (disseminated intravascular coagulation) (see also the information at the beginning of section 4)
- haemophagocytic lymphohistiocytosis (HLH) (see section 2 under: 'Special warnings regarding the use of the medicine')
- changes which may show up in blood tests - including reduced numbers of red blood cells (anaemia), reduced numbers of white blood cells (leucopenia, neutropenia, agranulocytosis), reduced numbers of platelets (thrombocytopenia), reduced numbers of all these types of cells (pancytopenia) and a disorder of the bone marrow called aplastic anaemia
- hallucinations ('seeing' or 'hearing' things that aren't really there)
- confusion
- feeling 'wobbly' or unsteady when you move about
- uncontrollable repeated body movements and/or sounds or words (tics), uncontrollable muscle spasms affecting the eyes, head and upper body (choreoathetosis) or other unusual body movements such as jerking, shaking or stiffness
- in people who already have epilepsy, seizures happening more often
- in people who have Parkinson's disease, worsening of the symptoms
- lupus-like reaction (symptoms may include: back or joint pain which sometimes may be accompanied by fever and/or general ill health).

Other side effects

Other side effects have occurred in a small number of users but their exact frequency is unknown:

- there have been reports of bone disorders including osteopenia and osteoporosis (thinning of the bone) and fractures. Check with your physician or pharmacist if you are on long-term anti-epileptic medication, have a history of osteoporosis or take steroids
- inflammation of the kidney (tubulointerstitial nephritis) or inflammation of both the kidney and the eye (tubulointerstitial nephritis and uveitis syndrome)
- nightmares
- decreased effectiveness of the immune system due to low levels of antibodies in the blood called immunoglobulins, which help protect against infection
- red nodules or patches on the skin (pseudolymphoma).

If a side effect has appeared, if any of the side effects get worse or when you suffer from a side effect that has not been mentioned in the leaflet, you should consult the physician.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

You can also report by email to: safety@trima.co.il

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.
- Do not use the medicine after the expiry date (exp. date) appearing on the package/blister. The expiry date refers to the last day of that month.
- Store in a dry place, below 30°C.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

- In addition to the active ingredient the medicine also contains the following inactive ingredients:
  Lactose (anhydrous), microcrystalline cellulose, sodium starch glycollate, colloidal silicon dioxide, magnesium stearate.
  Lamogine 25 mg contains 20 mg lactose.
  Lamogine 50 mg contains 40 mg lactose.
  Lamogine 100 mg contains 80 mg lactose.
  Lamogine 200 mg contains 160 mg lactose.
- **What the medicine looks like and the content of the package:**
  Lamogine 25 mg – round, white tablet.
  Lamogine 50 mg – round, white tablet with a score line on one side.
  Lamogine 100 mg – round, white tablet with a score line on one side.
  Lamogine 200 mg – oblong, white tablet with a score line on one side.
  Each pack contains 30 tablets.
- **Manufacturer and license holder:** Trima, Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000, Israel.
- Revised in November 2024.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Lamogine 25 mg	123.87.30352.00
Lamogine 50 mg	123.88.30353.00
Lamogine 100 mg	123.89.30354.00
Lamogine 200 mg	123.90.30355.00

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