PACKAGE LEAFLET: INFORMATION FOR THE USER
Lamoro 25 mg / 50 mg / 100 mg / 200 mg Dispersible Tablets
lamotrigine

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Lamoro Dispersible Tablets are and what they are used for
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1. WHAT LAMORO DISPERSIBLE TABLETS ARE AND WHAT THEY ARE USED FOR

Lamoro Dispersible Tablets contain the active ingredient lamotrigine, which belongs to a group of medicines called anti-epileptics and is used to treat Epilepsy and Bipolar disorder.

Lamoro Dispersible Tablets treats epilepsy by blocking the signals in the brain that trigger epileptic seizures (fits).
- For adults and children aged 13 years and over, Lamoro Dispersible Tablets can be used on its own or with other medicines, to treat epilepsy. Lamoro Dispersible Tablets can also be used with other medicines to treat the seizures that occur with a condition called Lennox-Gastaut syndrome.
- For children aged between 2 and 12 years, Lamoro Dispersible Tablets can be used with other medicines, to treat those conditions. It can be used on its own to treat a type of epilepsy called typical absence seizures.

Lamoro Dispersible Tablets also treats bipolar disorder.
People with bipolar disorder (sometimes called *manic depression)* have extreme swings with periods of mania (excitement or euphoria) alternating with periods of depression (deep sadness or despair). For adults aged 18 years and over, Lamoro Dispersible Tablets can be used on its own or with other medicines, to prevent the periods of depression that occur in bipolar disorder. It is not yet known how Lamoro Dispersible Tablets works in the brain to have this effect.

2. BEFORE YOU TAKE LAMORO DISPERSIBLE TABLETS

Do NOT take Lamoro Dispersible Tablets if you are:
- allergic (hypersensitive) to lamotrigine or any of the other ingredients of Lamoro Dispersible Tablets (*see Section 6 and end of Section 2*).

Take special care with Lamoro Dispersible Tablets.
Your doctor needs to know before you take Dispersible Tablets:
- **If you have kidney problems**
- **if you have ever developed a rash** after taking lamotrigine or other medicines for bipolar disorder or epilepsy
- **if you have ever developed meningitis after taking lamotrigine** *(read the description of these symptoms in Section 4 of this leaflet: Other side effects)*
- **if you are already taking medicine that contains lamotrigine.**

If any of these applies to you:
- **Tell your doctor,** who may decide to lower the dose, or that Lamoro Dispersible Tablets is not suitable for you.

Important information about potentially life-threatening reactions
A small number of people taking Lamoro Dispersible Tablets 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 Lamoro Dispersible Tablets.
- **Read the description of these symptoms in Section 4 of this leaflet** under '*Potentially life-threatening reactions: get a doctor's help straight away'.*

Thoughts of harming yourself or suicide
A small number of people with depression or bipolar disorder being treated with anti-epileptics such as Lamoro have also had thoughts of harming or killing themselves. If you have bipolar disorder, you may be more likely to think like this:
- when you first start treatment
- if you have previously had thoughts about harming yourself or committing suicide
- if you are under 25 years old.

If you have distressing thoughts or experiences, behave differently, feel worse or develop new symptoms whilst taking Lamoro Dispersible Tablets **contact your doctor immediately or go to the nearest hospital for help.**

If you're taking Lamoro for epilepsy
The seizures in some types of epilepsy may occasionally become worse or happen more often while you're taking Lamoro. 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 Lamoro: **See a doctor as soon as possible.**

Lamoro should not be given to 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.

Taking other medicines
Please tell your doctor or pharmacist if you are taking other medicines, have taken any recently, or start taking new ones - including those obtained without a prescription or herbal medicines.

Your doctor 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 dose of Lamoro, These medicines include:
- **oxcarbazepine, felbamate, gabapentin, levetiracetam, pregabalin, topiramate** or **zonisamide**, used to treat epilepsy
- **lithium** or **olanzapine,** used to treat mental health problems
- **bupropion,** used to treat mental health problems or to stop smoking

Some medicines interact with Lamoro or make it more likely that people will have side effects. These include:
- **valproate, carbamazepine** used to treat **epilepsy** and **mental health problems**
- **phenytoin, primidone** or **phenobarbitone,** used to treat **epilepsy**
- **risperidone, lithium** 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)
- oral contraceptives or hormone replacement therapy (HRT) drugs.

Hormonal contraceptives (such as the pill) can affect the way Lamoro works
Your doctor 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 hormonal contraceptive like the Pill, your doctor may take samples of your blood to check the level of Lamoro. If you are using a hormonal contraceptive, or if you plan to start using one:
- **Talk to your doctor,** who will discuss suitable methods of contraception with you. Lamoro can also affect the way hormonal contraceptives work, although it's unlikely to make them less effective. If you are using hormonal contraceptive and you notice any changes in your menstrual pattern, such as breakthrough bleeding or spotting between periods:
- **Tell your doctor.** These may be signs that Lamoro is affecting the way your contraceptive is working.

Pregnancy and breast-feeding
There may be an increased risk of birth defects in babies who took Lamoro during pregnancy. These defects may include cleft lip or cleft palate. Your doctor may advise you to take extra **folic acid** if you're planning to become pregnant and while you are pregnant. Pregnancy may also alter the effectiveness of Lamoro, so you may need blood tests and your dose of Lamoro may be adjusted.
- **Talk to your doctor if you're pregnant, if you might be pregnant, or if you're planning to become pregnant. You should not stop treatment without discussing this with your doctor.** This is particularly important if you have epilepsy.
- **Talk to your doctor if you're breast feeding or planning to breast feed**. The active ingredient of Lamoro passes into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of breast feeding while you're taking Lamoro, and will check your baby from time to time if you decide to breast feed.

Driving and using machines
You should see how Lamoro Dispersible Tablets affect you before driving or using machinery; as dizziness and blurred vision have been experienced.

Important information about some of the ingredients of Lamoro Dispersible Tablets
Lamoro Dispersible Tablets contain
- **aspartame E951**, a source of phenylalanine, which may be harmful for people with phenylketonuria (an enzyme deficiency disorder).

3. HOW TO TAKE LAMORO DISPERSIBLE TABLETS

Always take Lamoro Dispersible Tablets exactly as your doctor has told you. You should check with him/her if you are not sure. The dose your doctor will prescribe for you depends on whether you are taking Lamoro Dispersible Tablets on their own or with other anti-epileptic medicines and, if so, which ones. This is especially important if you are taking any medicine containing valproate or if you have kidney or liver problems.

General information
- It is usual for the dose of Lamoro Dispersible Tablets to start at quite a low level and to be slowly increased during the first few weeks of treatment. **Do not increase your dose** of Lamoro Dispersible Tablets **or take more frequent doses than those prescribed by your doctor.**
- If your child is taking these tablets, their weight should be checked and the dose reviewed as weight changes can occur.
- The pharmacist's label on your pack should tell you how many Lamoro Dispersible Tablets to take and how often. If you are not sure, ask your doctor or pharmacist.

The tablets should be chewed, or dissolved in a little water (enough to cover the tablet) or swallowed whole with a glass of water. You can take the tablets with or without food.

Epilepsy:

Adults and children aged 13 years or over: The usual dose is between 100 mg and 400 mg, taken once daily or in two divided doses.

Children between 2 and 12 years old: The effective dose depends on their body weight - usually, it's between 1 mg and 15 mg for each kilogram of the child's weight, up to a maximum of 200 mg daily

Children under 2 years: Lamoro Dispersible Tablets are not recommended for use in children under 2 years of age.

Bipolar Disorder:

Adults or elderly (18 years and over): The usual dose used is between 100 mg and 400 mg, taken once daily or in two divided doses. If you are taking Lamoro Dispersible Tablets to prevent extreme mood swings, you may not experience the full effect for several weeks.

Children (under 18 years): Lamoro Dispersible Tablets are not recommended for use in children under 18 years of age for the treatment of bipolar disorder.

If you take more Lamoro Dispersible Tablets than you should

If you take too many tablets, contact your doctor, pharmacist or go to your nearest casualty department. *Symptoms* of overdose include rapid/involuntary eye movements, loss of muscular co-ordination, unconsciousness or coma.

If you forget to take Lamoro Dispersible Tablets

Do not take a double dose to make up for a forgotten dose. Ask your doctor for advice on how to start taking it again. This is important.

Don't stop taking Lamoro without advice

Lamoro must be taken for as long as your doctor recommends. Don't stop unless your doctor advises you to.

If you're taking Lamoro for epilepsy

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

If you're taking Lamoro for bipolar disorder

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

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Lamoro Dispersible Tablets can cause side effects, although not everybody gets them.

Potentially life-threatening reactions: get a doctor's help straight away

A small number of people taking Lamoro get 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 Lamoro, especially if the starting dose is too high or if the dose is increased too quickly, or if Lamoro 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 life-threatening skin reactions including widespread rash with blisters and peeling skin, particularly occuring 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 (DRESS)
- **ulcers in the mouth, throat, nose or genitals**
- **a sore mouth or red or swollen eyes** (*conjuctivitis*)
- **a high temperature** (fever), flu-like symptoms or drowsiness
- **swelling around your face,** or **swollen glands** in your neck, armpit or groin
- **unexpected bleeding or bruising,** 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:

- **Contact a doctor immediately**. Your doctor may decide to carry out tests on your liver, kidneys or blood, and may tell you to stop taking Lamoro. In case you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis your doctor will tell you that you must never use lamotrigine again.

Very common (affecting more than 1 in 10 people)

- skin rash – usually occur within the first 8 weeks and are usually mild. If worried, please see a doctor.
- headache
- dizziness, feeling sleepy or drowsy
- blurred or double vision
- clumsiness and lack of co-ordination (ataxia)
- feeling sick (nausea) or being sick (vomiting)

Common (affecting up to 1 in 10 people)

- aggression
- irritability, agitation
- drowsiness, tiredness, sleepiness, insomnia
- nausea and gastrointestinal disturbances, including vomiting, diarrhoea and dry mouth
- rapid/involuntary eye movements, loss of muscular co-ordination, tremor
- back or joint pain, which may be accompanied by a fever and/or general lupus (ill health) feeling.

Rare (affecting up to 1 in 1,000 people)

- Stevens-Johnson syndrome (a type of skin reaction); potentially life-threatening
- itchy eyes, with discharge and crusty eyelids (conjunctivitis).

Very rare (affecting up to 1 in 10,000 people)

- hallucinations ('seeing' or 'hearing' things that aren't really there)
- confusion or agitation
- feeling 'wobbly' or unsteady when you move about
- uncontrollable body movements *(tics)*, uncontrollable muscle spasms affecting the eyes, head and torso *(choreoathetosis)*, or other unusual body movements such as jerking, shaking or stiffness
- a life-threatening skin reaction *(toxic epidermal necrolysis): see also the information at the beginning of section 4)*
- in people who already have epilepsy, seizures happening more often
- changes in liver function, which will show up in blood tests - including reduced numbers of red blood cells *(anaemia)*, reduced numbers of white blood cells (*leucopenia, neutropenia, agranulo-cystosis)*, reduced number of platelets *(thrombocytopenia)*, reduced numbers of all these types of cell (pancytopenia), and a disorder of the bone marrow called *aplastic anaemia*
- a serious disorder of blood clotting, which can cause unexpected bleeding or bruising *(disseminated intravascular coagulation)*
- a high temperature *(fever)*
- swelling around the face *(oedema)* or swollen glands in the neck, armpit or groin *(lymphadenopathy)*
- in people who already have Parkinson's disease, worsening of the symptoms.

Other side effects

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

A group of symptoms 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 doctor.**
- There have been reports of bone disorders including osteopenia and osteoporosis (thinning of the bone) and fractures. Check with your doctor or pharmacist if you are on long-term antiepileptic medication, have a history of osteoporosis, or take steroids
- DRESS

Suicidality

Occasionally, the symptoms of depression or bipolar disorder may include thoughts of harming yourself or committing suicide. Tell your doctor immediately or go to the nearest hospital if you have any distressing thoughts or experiences during treatment with Lamoro Dispersible Tablets.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE LAMORO DISPERSIBLE TABLETS

Keep out of the sight and reach of children.

Do not use Lamoro Dispersible Tablets after the expiry date ('EXP') stated on the carton and foil strip. The expiry date refers to the last day of that month.

There are no special storage recommendations for these tablets.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. FURTHER INFORMATION

What Lamoro Dispersible Tablets contain

The **active** ingredient is lamotrigine. Each dispersible tablet contains 25 mg, 50 mg, 100 mg or 200 mg of lamotrigine.

The **other** ingredients are: crospovidone, povidone K-30, mannitol (E421), silicified microcrystalline cellulose, aspartame (E951) (*see end of Section 2 for further information about aspartame*), croscarmellose sodium, black currant flavour and magnesium stearate.

What Lamoro Dispersible Tablets look like and contents of the pack

Lamoro Dispersible Tablets are round, white to off white coloured and plain on both sides. They are available in PVC/aluminium foil blister strips containing 7, 14, 28, 30, 56 or 60 tablets (not all pack sizes may be marketed).

Marketing Authorisation Holder and Manufacturer

Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary.

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