

LAMOTRIGINE NORMON CHEWABLE DISPERSIBLE TABLETS

Lamotrigine 50 mg/100 mg

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What Lamotrigine Normon Tablets are used for

Lamotrigine is derived from a group of medicines called antiepileptics. It is used for the treatment of two types of bipolar diseases: epilepsy and bipolar disorder.

Epilepsy:

Lamotrigine Normon blocks the signals to the brain that may cause epileptic seizures (fit).

- In adults and children aged 13 years and over, Lamotrigine can be taken by itself or in combination with other medicines to treat epilepsy, and seizures caused by a disease called Lennox-Gastaut syndrome.
- For children aged 2 to 12 years, Lamotrigine can be taken by itself or in combination with other medications to treat the same diseases. It can also be used alone for the treatment of a type of epilepsy called 'typical absence seizures'.

Bipolar disorder:

People with bipolar disorder (formerly known as manic depressive disorder) experience extreme mood swings, with periods of mania (excitation or euphoria) alternating with periods

of depression (deep sorrow or desperation). In adults aged 18 years and above, Lamotrigine Normon can be used alone or in combination with other drugs to prevent the depression in bipolar disorder.

How Lamotrigine Normon Tablets work

Lamotrigine Normon can be used alone or in combination with other drugs to prevent the depression in bipolar disorder. It is not known how Lamotrigine works in the brain to provide the above effects.

What you need to know before you use Lamotrigine Normon Tablets

When you must not take it

If you are allergic to Lamotrigine or any other ingredient of this medicine (see Section on Product Description'). Please inform your doctor and do not take Lamotrigine Normon.

Before you start to take it

Tell your doctor if you have any of the following conditions:

- if you have any 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 *Side effects section*)
- if you are already taking other medicines containing Lamotrigine.

If you take Lamotrigine Normon for epilepsy

The seizures in some types of epilepsy may occasionally become worse or happen more often while you're taking Lamotrigine Normon. 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 Lamotrigine Normon, see a doctor as soon as possible.

Lamotrigine Normon should not be given to children under the age of 18 years to treat bipolar disorder. Drugs indicated for the treatment of depression or other mental health problems increase the risk of thoughts of self-harm and suicidal behaviour in children under the age of 18.

Pregnancy and Breastfeeding

- If you are pregnant, think you may be pregnant or are planning to have a baby ask your doctor or pharmacist for advice before taking this medicine.
 - You should not stop treatment without discussing this with your doctor. This is particularly important if you have epilepsy.
 - Pregnancy may alter the effectiveness of Lamotrigine Normon, so you may need blood tests and your dose may be adjusted.
 - There may be a small increased risk of birth defects, including a cleft lip or cleft palate, if Lamotrigine Normon is taken during the first 3 months of pregnancy.
 - Your doctor may advise you to take extra folic acid if you're planning to become pregnant and while you're pregnant.

- If you are breastfeeding or plan to breastfeed ask your doctor or pharmacist for advice before taking this medicine. The active ingredient of Lamotrigine Normon passes into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of breast-feeding while taking Lamotrigine Normon and will check your baby from time to time if you decide to breast-feed, as your baby may experience

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drowsiness, rash or little weight gain. Contact your doctor if you observe any of these symptoms in your baby.

Driving and Handling Machines
Lamotrigine can cause dizziness and double vision.

- Do not drive or use machines unless you are sure you are not affected.

If you have epilepsy, talk to your doctor about driving or operating machinery.

Brugada's syndrome

Brugada's syndrome is a genetic disease causing abnormal electrical activity of the heart. Lamotrigine can lead to abnormalities in the electrocardiogram (ECG) that can cause arrhythmias (abnormal heart rhythm). Talk to your doctor if you have this disease.

Hemophagocytic

lymphohistiocytosis (HLH)

There have been reports of a rare but very serious reaction of the immune system in patients taking Lamotrigine. Contact your doctor or pharmacist immediately if you experience any of the following symptoms while taking Lamotrigine: fever, rash, neurological symptoms (e.g., shaking or tremors, confusional state, impaired brain function).

Taking other medicines

Please tell your doctor or pharmacist if you are taking have recently taken or might take any other medicines, including medicines 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 Lamotrigine Normon. 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)

Tell your doctor if you are taking any of these.

Some medicines interact with Lamotrigine or make side effects more likely. Tell your doctor if you are using, or start or stop using, any of the following:

- 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 the Pill) can affect the way Lamotrigine Normon 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 a hormonal contraceptive like the Pill, your doctor 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 doctor, who will discuss

suitable methods of contraception with you. Lamotrigine 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 doctor. These may be signs that Lamotrigine is affecting the way your contraceptive is working.

How to take Lamotrigine Normon Tablets

How much to take

Take the medicine exactly as advised by your doctor. Check with your doctor or pharmacist if you are not sure. It may take a while to find the best dose of Lamotrigine Normon for you. The dose you take will depend on:

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

Your doctor will start your treatment with a low dose and gradually increase it over a few weeks until you reach the suitable dose (called the effective dose) of Lamotrigine Normon for you. Never take more Lamotrigine Normon than your doctor tells you to.

The usual effective dose of Lamotrigine Normon for adults and children aged 13 years or over is between 100 mg to 400 mg per day.

For children aged 2 to 12 years, the effective dose depends on body weight, usually, it's between 1 mg and 15 mg for each kilogram of the child's weight, up to a maximum maintenance dose of 200 mg daily.

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Lamotrigine Normon is not recommended for children aged under 2 years.

How to take it

Take Lamotrigine Normon once or twice a day, as your doctor advises. Always take the full dose prescribed by your doctor. Never take only part of a tablet.

Your doctor 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.

You can take Lamotrigine Normon with or without food. Lamotrigine Normon Chewable Dispersible Tablets can either be swallowed whole with a little water, chewed or mixed with water to make a liquid medicine.

Chewing the tablet:

You might need to drink a little water to help dissolve the tablet after chewing. Drink a little more water after swallowing it, to ensure you have taken the whole dose.

Dissolving the tablet:

1. Put the tablet in a glass with at least enough water to cover the whole tablet.
2. Either stir to dissolve or wait until the tablet is fully dissolved.
3. Drink all the liquid.
4. Rinse the glass with a little more water and drink it, to make sure no medicine is left in the glass.

How long to take it

Take Lamotrigine Normon for the time your doctor recommends. Do not stop taking this medicine unless told to do so by your doctor.

If you forget to take it

Do not take a double dose to make up for a missed dose. Just take your next dose at the usual time.

Consult your doctor or pharmacist if you are unsure. In case you forget to take multiple doses of Lamotrigine Normon: Ask your doctor for advice on how to start taking it again. It's important that you do this.

If you take too much (overdose)

Consult your doctor or pharmacist immediately; if possible, show them the packaging of Lamotrigine Normon.

If you take more Lamotrigine Normon than you should you may be more likely to have serious side effects which may be fatal. Someone who has taken too much Lamotrigine Normon may have the following symptoms:

- Rapid and uncontrollable eye movements (nystagmus)
- Clumsiness and loss of coordination, affecting balance (ataxia)
- Heart rhythm changes (detected usually on ECG)
- Loss of consciousness, convulsions or coma

While you are taking Lamotrigine Normon Tablets

Things you must do

Follow the instructions for the administration of Lamotrigine Normon exactly as your doctor tells you. Ask your doctor or pharmacist if you have any doubts.

Important information about potentially life-threatening reactions

A small number of people taking Lamotrigine get an allergic reaction or potentially life-threatening skin reactions, 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 of these reactions to

look out for while you are taking Lamotrigine Normon.

Read the description of these symptoms in section on 'Side Effects' of this leaflet "Potentially life-threatening reactions: get a doctor's help straight away".

Thoughts of Self Harm or Suicide

People with bipolar disorder (and some with epilepsy) being treated with Lamotrigine Normon may occasionally have thoughts of self-harm or suicide, especially in the following situations:

- When first starting treatment
- If you have had thoughts of self-harm or suicide
- If you are under the age of 25 years

If you have troubling thoughts or experiences, or if you start to feel bad or experience new symptoms during treatment with Lamotrigine Normon:

- Tell your doctor immediately or go to the nearest hospital.

You may find it helpful to tell a family member, caregiver or close friend that you can become depressed or have significant changes in mood, and ask them to read this leaflet. You might ask them to tell you if they are worried about your depression or other changes in your behavior. A small number of people being treated with anti-epileptics such as Lamotrigine Normon have also had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

Things you must not do

Do not stop taking Lamotrigine Normon without the advice of your doctor. Lamotrigine Normon must be taken for as long as your doctor recommends. Do not stop taking this medicine unless your doctor tells you to.

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Things to be careful of

If you are taking Lamotrigine Normon to treat epilepsy

To stop taking Lamotrigine Normon it is important that the dose to be reduced gradually, over about two weeks. If you stop taking Lamotrigine Normon suddenly, you may suffer from the symptoms of epilepsy again or the disease may worsen.

If you are taking Lamotrigine Normon for bipolar disorder
Lamotrigine Normon may take a while to work, so you are unlikely to feel an immediate improvement. If you stop taking Lamotrigine Normon, your dose will not need to be reduced gradually but you should still talk to your doctor first, if you want to stop taking Lamotrigine Normon.

Side Effects

Like all drugs, this medicine can produce adverse effects, although not everyone suffers from them. Potentially life-threatening reactions: get a doctor's help straight away.

A small number of people who take Lamotrigine have potentially severe allergic or skin reactions, 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 Lamotrigine Normon, especially if the starting dose is too high or if the dose is increased too quickly or if Lamotrigine Normon 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 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 DRESS hypersensitivity syndrome).

- 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 somnolence
- Swelling around the face or swollen glands in your neck, armpits or groin
- Unexpected bleeding or bruising, or 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 may be signs of less severe adverse 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 Lamotrigine Normon. 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 Side Effects. These may affect more than 1 in 10 people:

- Headache
- Skin rash

Common Side Effects. These may affect up to 1 in 10 people:

- Aggression or irritability
- Feeling sleepy or drowsy
- Feeling dizzy
- Spasms or tremor
- Difficulty in sleeping (insomnia)
- Feeling agitated
- Diarrhoea
- Dry mouth
- Nausea or vomiting
- Feeling tired
- Pain in the back, joints or other areas

Uncommon side effects. These may affect up to 1 in 100 people:

- Clumsiness and lack of co-ordination (ataxia)
- Double vision or blurred vision
- Unusual hair loss or thinning (alopecia)

Rare side effects. These may affect up to 1 in 1,000 people:

- A life-threatening skin reaction (*Stevens-Johnson syndrome*) (*see also the information at Important information about potentially life-threatening reactions*)
- 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

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- Rapid, uncontrollable eye movements (*nystagmus*)
- Itchy eyes, with discharge and crusty eyelids (*conjunctivitis*).

Very rare side effects. These may affect up to 1 in 10,000 people:

- A life-threatening skin reaction (*toxic epidermal necrolysis*) (*see also the information at the beginning of Side effects section*)
- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) (*see also the information at the beginning of Side effects section*)
- A high temperature (*fever*) (*see also the information at the beginning of Side effects section*)
- Swelling around the face (*edema*) or swollen glands in the neck, armpit or groin (*lymphadenopathy*) (*see also the information at the beginning of Side effects section*)
- Changes in liver function, which will show up in blood tests or liver failure (*see also the information at the beginning of Side effects section*)
- A serious disorder of blood clotting, which can cause unexpected bleeding or bruising (*disseminated intravascular coagulation*) (*see also the information at the beginning of Side effects section*)
- Changes which may show up in blood tests - including reduced numbers of red blood cells (*anemia*), reduced numbers of white blood cells (*leukopenia*, *neutropenia*, *agranulocytosis*), reduced numbers of platelets (*thrombocytopenia*), reduced numbers of all these types of cell (*pancytopenia*) and a disorder of the bone marrow called aplastic anemia

- Hallucinations ('seeing' or 'hearing' things that aren't really there)
- Confusion
- 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
- In people who already have epilepsy, seizures happening more often
- In people who already 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)
- Hemophagocytic lymphohistiocytosis (HLH) (*see also information at What you need to know before you use Lamotrigine Normon Tablets*)

Other side effects

Other side effects have occurred in a small number of people 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 doctor or pharmacist if you are on long-term anti-epileptic medication, have a history of osteoporosis or take steroids
- Nightmares
- Decreased immunity, due to the reduction in the levels of antibodies called immunoglobulins in the blood that help protect against infection (*see also information at What you need to know before you use Lamotrigine Normon Tablets*).

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.moh.gov.my [Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]. By reporting side effects, you can help provide more information on the safety of this medicine.

Storage and Disposal of Lamotrigine Normon Tablets

Storage

Store below 30°C, in the original carton to protect the medication. Keep this medicine out of the sight and reach of children.

Disposal

Do not use after the expiry date stated on the label.

Return any unused tablets to your pharmacist to be disposed of. Only keep the tablets if your doctor tells you to. Do not throw them away in your normal household drainage or waste. This will help to protect the environment.

Product Description

What it looks like

Lamotrigine Normon 50 mg is white or almost white, biconvex and round dispersible tablets. The weight of the 50 mg tablet is 130 mg and the diameter is 7.65 mm. Lamotrigine Normon 100 mg is a white or almost white, biconvex and round dispersible tablet. The weight of the 100 mg tablet is 260 mg and the diameter is 9.65 mm.

Ingredients

Active Ingredient

The active ingredient is Lamotrigine.

Each Lamotrigine Normon 50 mg Chewable Dispersible Tablet contains 50 mg Lamotrigine.

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Each Lamotrigine Normon 100 mg Chewable Dispersible Tablet contains 100 mg Lamotrigine.

Inactive ingredients

Crospovidone, saccharin sodium (E-954), orange flavor (aroma, corn maltodextrin, D- tocopherol (E-307) and benzyl alcohol), magnesium stearate and colloidal anhydrous silica.

MAL Number

Lamotrigine Normon 50 mg
Chewable Dispersible Tablet:
MAL13055055AZ

Lamotrigine Normon 100 mg
Chewable Dispersible Tablet:
MAL12085059AZ

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