

LAMOTRIGINE NORMON CHEWABLE DISPERSIBLE TABLETS

Lamotrigine 50mg/100mg

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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 the diseases: epilepsy and bipolar disorder.

Epilepsy:

Lamotrigine NORMON blocks the signals to the brain that may cause convulsions (seizures).

- In adults and children older than 13 years, Lamotrigine can be taken by itself or in combination with other medicines to treat epilepsy, and convulsions 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 radical 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.

Before you use Lamotrigine NORMON Tablets

When you must not take it

If you are allergic to lamotrigine or any other ingredient in Lamotrigine NORMON (see Section on 'Product Description'). Please inform your doctor and do not take Lamotrigine NORMON.

Before you start to take it

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

- kidney disease
- you have ever had a rash while taking lamotrigine or other drugs for epilepsy
- you are taking other medicines containing lamotrigine.

If you take Lamotrigine NORMON for epilepsy

In some forms of epilepsy, convulsions may get worse or happen more often during treatment with Lamotrigine NORMON. Some patients may experience very serious convulsions. If you suffer fits more often, or if you have a serious fit when taking Lamotrigine NORMON, see a doctor immediately.

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

- Tell your doctor if you are pregnant or plan to become pregnant.

Epilepsy treatment should not be stopped during pregnancy. However, there is a higher risk of birth defects in babies born to women who took lamotrigine during pregnancy. These defects include a hair lip or cleft palate. Your doctor may advise you to take supplements of folic acid if you are planning to become pregnant or are pregnant. Pregnancy can alter the effectiveness of lamotrigine, so your doctor may test the levels of lamotrigine in your blood and then adjust your dose.

- Talk to your doctor if you are breastfeeding or plan to breastfeed. Lamotrigine enters breast milk and may affect your child. Your doctor will discuss the risks and benefits of breastfeeding while taking Lamotrigine. If you are breastfeeding, your doctor will conduct regular checks on your baby.

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

- Do not drive or operate hazardous machinery until you know that you do not feel these symptoms.

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

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Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken other medicines, including medicines obtained without a prescription, or herbal medicines.

Some drugs will affect the dose of Lamotrigine NORMON you need. If you are taking any of the medications below, please inform your doctor:

- Oxcarbazepine, felbamate, gabapentin, levetiracetam, pregabalin, topiramate or zonisamide (used to treat epilepsy)
- Lithium (to treat mental problems)
- bupropion (to treat mental problems or help stop smoking)

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 or carbamazepine (to treat epilepsy and mental problems)
- Phenytoin, primidone or phenobarbitone (to treat epilepsy)
- Olanzapine or risperidone (for mental problems)
- Rifampicin (an antibiotic)
- The combination of lopinavir and ritonavir (to treat infection with HIV (Human immunodeficiency virus))
- Hormonal contraception, such as 'the Pill'. This may interfere with the action of Lamotrigine. Discuss with your doctor the choices of a suitable hormonal contraceptive or a different method of contraception such as a condom, diaphragm or IUD. If you are using a hormone contraceptive, and observe

changes in your period, such as intermenstrual bleeding or stains between periods, inform your doctor. This could be a sign that lamotrigine is disrupting the action of the contraceptive.

How to take Lamotrigine NORMON Tablets

How much to take

Take the medicine exactly as advised by your doctor. Your doctor will start your treatment with a low dose and gradually increase it to achieve the suitable dose of Lamotrigine NORMON for you.

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

For children aged 2 to 12 years, the effective dose depends on body weight, with a maximum dose of 400mg per day.

When to take it

Take Lamotrigine NORMON one or two times a day, as advised by your doctor. Always take the full dose prescribed by your doctor.

You can take Lamotrigine NORMON with or without food. Take the tablet by swallowing whole, chewing, or dissolving it in water.

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 the just enough water to cover the tablet.

2. Stir to dissolve or wait for one minute until the tablet is completely dissolved.
3. Drink all the liquid.
4. Rinse the glass with a little more water and drink it, to ensure that you have taken the whole dose.

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 double the dose to make up for a missed dose. Take your next dose at the appropriate time. Consult your doctor or pharmacist if you are unsure.

If you take too much (overdose)

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

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)
- Loss of consciousness 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.

Seek help from your doctor immediately if you experience any unwanted symptoms such as rash, fever, sore throat or

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bruising (see full list in section on 'Side Effects') after starting treatment with Lamotrigine:

These symptoms are more likely to appear during the first month of treatment with lamotrigine, especially if you begin treatment with high doses or dose is increased too quickly. The symptoms are also more likely if you take Lamotrigine along with another drug called valproate. Children are more likely than adults to experience these side effects. If the above symptoms are not treated, it may lead to more serious problems, such as organ failure or serious skin problems.

Ideas of Self Harm or Suicide

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

- When first starting treatment
- If you have had ideas 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.

Things you must not do

Do not stop taking Lamotrigine NORMON unless told to do so by your doctor.

Things to be careful of

If you are taking Lamotrigine NORMON to treat epilepsy

To stop taking Lamotrigine NORMON it is important for the dose to be reduced gradually, over approximately

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. To stop taking Lamotrigine Normon, the dose does not need to be reduced gradually. However, before stopping treatment with Lamotrigine Normon, you should consult your doctor.

Side Effects

Like all drugs, Lamotrigine NORMON can produce adverse effects, although not everyone suffers from them.

Potentially severe allergic reactions or skin reactions: consult a doctor immediately.

A small number of people who take lamotrigine have potentially severe allergic or skin reactions. If not treated, these reactions can become worse and may even be fatal. These reactions include:

- Rash or reddening of the skin
- Ulcers and pain in the mouth or eyes
- High temperature (fever), symptoms similar to flu or somnolence
- Swelling around the face or inflammation of the glands in the neck, armpits or groin
- Bleeding or unexpected bruises, or fingers turning blue
- Sore throat or more infections (such as colds) than normal

In many cases, these symptoms may be signs of less severe adverse effects. But you should realise that they are potentially serious – if you suffer any of

these symptoms, see a doctor immediately.

Very Frequent Adverse Effects

- Headache
- Dizziness
- Sensation of sleep or somnolence
- Clumsiness and loss of coordination (ataxia)
- Double-vision or blurred vision
- Nausea or vomiting
- Rash

Frequent Adverse Effects

- Aggression, irritability
- Rapid and uncontrollable eye movements (nystagmus)
- Spasms or tremor
- Difficulty in sleeping
- Diarrhoea
- Dry mouth
- Tiredness
- Pain in the back, joints or other areas.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and Disposal of Lamotrigine NORMON Tablets

Storage

Store below 30°C, in the original carton to protect the medication.

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.

LAMOTRIGINE NORMON CHEWABLE DISPERSIBLE TABLETS

Lamotrigine 50mg/100mg

Product DescriptionWhat it looks like

Lamotrigine NORMON 50mg is white or almost white, biconvex and round dispersible tablets. The weight of the 50mg tablet is 130 mg and the diameter is 7.65 mm.

Lamotrigine NORMON 100mg is a white or almost white, biconvex and round dispersible tablet. The weight of the 100mg tablet is 260 mg and the diameter is 9.65 mm.

Date of Revision

22-09-2014

Serial Number

BPFK(R4/1)220914/00020

IngredientsActive Ingredient

The active ingredient is lamotrigine.

Each Lamotrigine NORMON 50mg Chewable Dispersible Tablet contains 50mg lamotrigine.

Each Lamotrigine NORMON 100mg Chewable Dispersible Tablet contains 100mg lamotrigine.

Inactive ingredients

Crospovidone, saccharin sodium (E-954), intipati oren (aroma, corn maltodextrin, D-tocopherol (E-307) dan benzyl alcohol), magnesium stearate, dan colloidal silica.

MAL Number

Lamotrigine NORMON 50mg
Chewable Dispersible Tablet:
MAL13055055A

Lamotrigine NORMON 100mg
Chewable Dispersible Tablet:
MAL12085059A

Manufacturer**Laboratorios NORMON, S.A.**

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Product Registration Holder**Actavis Sdn Bhd**

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