

Package leaflet: information for the user

Lamotrigine Normon 50 mg dispersible/chewable tablets

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

Contents of the leaflet:

1. What Lamotrigine Normon is and what it is used for
2. What you need to know before you take Lamotrigine Normon
3. How to take Lamotrigine Normon
4. Possible side effects
5. How to store Lamotrigine Normon
6. Contents of the pack and other information

1. What Lamotrigine Normon is and what it is used for

Lamotrigine Normon belongs to a group of medicines called *anti-epileptics*. It is used to treat two conditions: epilepsy and bipolar disorder.

Lamotrigine Normon is used for the treatment of epilepsy because it blocks the signals in the brain that trigger epileptic seizures (fits).

- For adults and children aged 13 years and over, lamotrigine can be used on its own or with other medicines to treat epilepsy. Lamotrigine 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, lamotrigine 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.

Lamotrigine Normon is also used for the treatment of bipolar disorder.

People with bipolar disorder (sometimes called manic depression) have extreme mood swings, with periods of mania (excitement or euphoria) alternating with periods of depression (deep sadness or despair). For adults aged 18 years and over, Lamotrigine Normon 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 lamotrigine works in the brain to have this effect.

2. What you need to know before you take Lamotrigine Normon

Do not take Lamotrigine Normon:

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

If this applies to you:

Tell your doctor and do not take Lamotrigine Normon.

Warnings and precautions

Talk to your doctor or pharmacist before taking Lamotrigine Normon.

- **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 section 4 of this leaflet: Rare side effects),
- **if you are already taking medicines that contain lamotrigine,**
- if you have ever developed a rash after taking lamotrigine or other medicines for bipolar disorder or epilepsy; or if you experience a rash or sunburn after taking lamotrigine and having been exposed to sun or artificial light (e.g. solarium). Your doctor will check your treatment and may advise you to avoid sunlight or protect yourself against the sun (e.g. use of a sunscreen and/or to wear protective clothing).

If any of these applies to you:

Tell your doctor, who may decide to lower the dose or that Lamotrigine Normon 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 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 4 of this leaflet “*Potentially life-threatening reactions: get a doctor’s help straight away*”.

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 thoughts of harming themselves or committing suicide. If you have bipolar disorder, you may be more likely to think like this in the following situations:

- when you first start treatment,
- if you have 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 are taking Lamotrigine Normon:

See a doctor as soon as possible or go to the nearest hospital for help.

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 behaviour.

A small number of people being treated with anti-epileptics such as lamotrigine have also had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

If you are taking Lamotrigine Normon for epilepsy

The seizures in some types of epilepsy may occasionally become worse or happen more often while you are 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 are taking Lamotrigine Normon:

See a doctor as soon as possible.

Lamotrigine Normon 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.

Other medicines and Lamotrigine Normon

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including herbal medicines or other medicines bought without a prescription.

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 medicines.

Some medicines interact with Lamotrigine Normon 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 phenobarbital**, 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 (AIDS)** (a combination of lopinavir and ritonavir or atazanavir and ritonavir),
- **hormonal contraceptives**, such as **the Pill** (*see below*).

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

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 is 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.

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.

Haemophagocytic 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).

Pregnancy and breast-feeding

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 and/or cleft palate, if Lamotrigine Normon is taken during the first 3 months of pregnancy.
- Your doctor may advise you to take extra **foliac acid** if you are planning to become pregnant and while you are pregnant.

If you are breast-feeding or planning to breast-feed 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 you are taking Lamotrigine Normon and will check your baby regularly if you decide to breast-feed, as your baby may experience drowsiness, rash or little weight gain. Contact your doctor if you observe any of these symptoms in your baby.

Driving and using machines

Lamotrigine Normon 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 and using machines.

Lamotrigine Normon contains glucose, benzyl alcohol, and sodium

This medicinal product contains glucose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. It may harm your teeth.

This medicine contains 0.00052 mg of benzyl alcohol per tablet.

Benzyl alcohol may cause allergic reactions.

Talk to your doctor or pharmacist if you are pregnant or breast-feeding. This is because large amounts of benzyl alcohol can accumulate in your body and cause side effects (metabolic acidosis).

Talk to your doctor or pharmacist if you have any liver or kidney disease. This is because large amounts of benzyl alcohol can accumulate in the body and cause side effects (metabolic acidosis).

Benzyl alcohol has been linked to the risk of serious side effects including breathing problems ("gaspings syndrome") in children.

Do not give this medicine to your new-born baby (up to 4 weeks of age) unless your doctor has recommended it.

This medicine should not be used for more than one week in children under 3 years of age unless directed by your doctor or pharmacist.

This medicine contains less than 23 mg sodium (1 mmol) per tablet; that is, essentially "sodium-free".

3. How to take Lamotrigine Normon

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much Lamotrigine Normon to take

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 prescribe a low dose to start and gradually increase the dose over a few weeks until you reach a dose that works for you (called the *effective dose*). **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 and 400 mg daily.

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

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

How to take your dose of Lamotrigine Normon

Take your dose of Lamotrigine Normon once or twice a day, as your doctor advises. It can be taken with or without food.

- **Always take the full dose** that your doctor has prescribed. 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 are being treated for and the way you respond to treatment.

Lamotrigine Normon dispersible/chewable tablets can be swallowed whole with a little water, chewed or mixed with water to make a liquid medicine.

To chew the tablet:

You may need to drink a little water at the same time to help the tablet dissolve in the mouth. Then drink some more water to make sure all the medicine has been swallowed.

To make a liquid medicine:

- put the tablet in a glass with at least enough water to cover the whole tablet,
- either stir to dissolve or wait until the tablet is fully dissolved,
- drink all the liquid,
- add a little more water to the glass and drink that, to make sure no medicine is left in the glass.

If you take more Lamotrigine Normon than you should

In case of overdose or accidental ingestion, contact to your doctor or pharmacist at once, or go to the nearest hospital, indicating the medicine and the amount taken.

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 any of these symptoms:

- rapid, uncontrollable eye movements (nystagmus),
- clumsiness and lack of co-ordination, affecting their balance (ataxia),
- heart rhythm changes (detected usually on ECG),
- loss of consciousness, convulsions or coma.

If you forget to take Lamotrigine Normon

Do not take a double dose to make up for a forgotten dose. **Carry on as usual the next day.**

In case you forget to take multiple doses of Lamotrigine Normon:

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

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.

If you are taking Lamotrigine Normon for epilepsy

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

If you are taking Lamotrigine Normon for bipolar disorder

Lamotrigine Normon may take some time to work, so you are unlikely to feel better straight away. 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.

4. Possible side effects

Like all medicines, this medicine 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 lamotrigine get an allergic reactions or potentially life-threatening 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 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 (sleepiness),
- **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 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
- shaking or tremors
- difficulty in sleeping (*insomnia*)
- feeling agitated
- diarrhoea
- dry mouth
- nausea or vomiting
- feeling tired
- pain in your back, joints, or elsewhere

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*)
- skin rash or sunburn after exposure to sun or artificial light (*photosensitivity*)

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 the beginning of section 4*)
- 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**
- 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 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 (*lymphadenopathy*) (*see also the information at the beginning of section 4*)
- changes in liver function, which will show up in blood tests or liver failure (*see also the information at the beginning of section 4*)
- a serious disorder of blood clotting, which can cause unexpected bleeding or bruising (*disseminated intravascular coagulation*) (*see also the information at the beginning of section 4*)
- changes which may show up in blood tests - including reduced numbers of red blood cells (*anaemia*), 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 anaemia
- hallucinations ('seeing' or 'hearing' things that are not 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)
- Haemophagocytic lymphohistiocytosis (HLH) (see section 2. What you need to know before you take lamotrigine)

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.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lamotrigine Normon

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the container. The expiry date refers to the last day of that month.

Store below 25°C. Store in the original package in order to protect from light and moisture.

Do not throw away any medicines via wastewater or household waste. If you are not sure, ask your pharmacist how to throw away medicines and containers you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Lamotrigine Normon 50 mg dispersible/chewable tablets contain

The active substance is lamotrigine. Each dispersible/chewable tablet contains 50 mg of lamotrigine.

The other ingredients are: Crospovidone, sodium saccharin (E-954), orange essence (contains glucose and benzyl alcohol), magnesium stearate and colloidal silica.

What Lamotrigine Normon looks like and contents of the pack

Lamotrigine Normon 50 mg dispersible/chewable tablets are white or almost white, biconvex and round dispersible/chewable tablets.

Each pack contains blisters of 42 or 56 dispersible/chewable tablets.

Not all pack sizes are marketed in all countries.

Marketing Authorization Holder and Manufacturer

LABORATORIOS NORMON, S.A.

Ronda de Valdecarrizo, 6 – 28760 Tres Cantos – Madrid (SPAIN)

This leaflet was last revised in: February 2021

Package leaflet: information for the user

Lamotrigine Normon 100 mg dispersible/chewable tablets

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- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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1. What Lamotrigine Normon is and what it is used for

Lamotrigine Normon belongs to a group of medicines called *anti-epileptics*. It is used to treat two conditions: **epilepsy** and **bipolar disorder**.

Lamotrigine Normon is used for the treatment of epilepsy because it blocks the signals in the brain that trigger epileptic seizures (fits).

- For adults and children aged 13 years and over, lamotrigine can be used on its own or with other medicines to treat epilepsy. Lamotrigine 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, lamotrigine 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.

Lamotrigine Normon is also used for the treatment of bipolar disorder.

People with bipolar disorder (sometimes called *manic depression*) have extreme mood swings, with periods of mania (excitement or euphoria) alternating with periods of depression (deep sadness or despair). For adults aged 18 years and over, Lamotrigine Normon 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 lamotrigine works in the brain to have this effect.

2. What you need to know before you take Lamotrigine Normon

Do not take Lamotrigine Normon:

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

If this applies to you:

Tell your doctor and do not take Lamotrigine Normon.

Warnings and precautions

Talk to your doctor or pharmacist before taking Lamotrigine Normon:

- **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 section 4 of this leaflet: *Rare side effects*),
- **if you are already taking medicines that contain lamotrigine,**
- if you have ever developed a rash after taking lamotrigine or other medicines for bipolar disorder or epilepsy; or if you experience a rash or sunburn after taking lamotrigine and having been exposed to sun or artificial light (e.g. solarium). Your doctor will check your treatment and may advise you to avoid sunlight or protect yourself against the sun (e.g. use of a sunscreen and/or to wear protective clothing).

If any of these applies to you:

Tell your doctor, who may decide to lower the dose or that Lamotrigine Normon is not suitable for you.

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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 4 of this leaflet “*Potentially life-threatening reactions: get a doctor’s help straight away*”.

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 thoughts of harming themselves or committing suicide. If you have bipolar disorder, you may be more likely to think like this in the following situations:

- when you first start treatment,
- if you have 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 are taking Lamotrigine Normon:

See a doctor as soon as possible or go to the nearest hospital for help.

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 behaviour.

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If you are taking Lamotrigine Normon for epilepsy

The seizures in some types of epilepsy may occasionally become worse or happen more often while you are 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 are taking Lamotrigine Normon:

See a doctor as soon as possible.

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Other medicines and Lamotrigine Normon

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including herbal medicines or other medicines bought without a prescription.

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 medicines.

Some medicines interact with Lamotrigine Normon 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 phenobarbital,** 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 (AIDS)** (a combination of lopinavir and ritonavir or atazanavir and ritonavir),
- **hormonal contraceptives,** such as **the Pill** (*see below*).

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

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 is 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.

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.

Haemophagocytic 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).

Pregnancy and breast-feeding

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 and/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 are planning to become pregnant and while you are pregnant.

If you are breast-feeding or planning to breast-feed 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 you are taking Lamotrigine Normon and will check your baby regularly if you decide to breast-feed, as your baby may experience drowsiness, rash or little weight gain. Contact your doctor if you observe any of these symptoms in your baby.

Driving and using machines

Lamotrigine Normon 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 and using machines.

Lamotrigine Normon contains glucose, benzyl alcohol, and sodium

This medicinal product contains glucose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. It may harm your teeth.

This medicine contains 0.00104 mg of benzyl alcohol per tablet.

Benzyl alcohol may cause allergic reactions.

Talk to your doctor or pharmacist if you are pregnant or breast-feeding. This is because large amounts of benzyl alcohol can accumulate in your body and cause side effects (metabolic acidosis).

Talk to your doctor or pharmacist if you have any liver or kidney disease. This is because large amounts of benzyl alcohol can accumulate in the body and cause side effects (metabolic acidosis).

Benzyl alcohol has been linked to the risk of serious side effects including breathing problems ("gasping syndrome") in children.

Do not give this medicine to your new-born baby (up to 4 weeks of age) unless your doctor has recommended it.

This medicine should not be used for more than one week in children under 3 years of age unless directed by your doctor or pharmacist.

This medicine contains less than 23 mg sodium (1 mmol) per tablet; that is, essentially "sodium-free".

3. How to take Lamotrigine Normon

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much Lamotrigine Normon to take

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 prescribe a low dose to start and gradually increase the dose over a few weeks until you reach a dose that works for you (called the effective dose). **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 and 400 mg daily.

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

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

How to take your dose of Lamotrigine Normon

Take your dose of Lamotrigine Normon once or twice a day, as your doctor advises. It can be taken with or without food.

- **Always take the full dose** that your doctor has prescribed. 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 are being treated for and the way you respond to treatment.

Lamotrigine Normon dispersible/chewable tablets can be swallowed whole with a little water, chewed or mixed with water to make a liquid medicine.

To chew the tablet:

You may need to drink a little water at the same time to help the tablet dissolve in the mouth. Then drink some more water to make sure all the medicine has been swallowed.

To make a liquid medicine:

- put the tablet in a glass with at least enough water to cover the whole tablet,
- either stir to dissolve or wait until the tablet is fully dissolved,
- drink all the liquid,
- add a little more water to the glass and drink that, to make sure no medicine is left in the glass.

If you take more Lamotrigine Normon than you should

In case of overdose or accidental ingestion, contact to your doctor or pharmacist at once, or go to the nearest hospital, indicating the medicine and the amount taken.

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 any of these symptoms:

- rapid, uncontrollable eye movements (nystagmus),
- clumsiness and lack of co-ordination, affecting their balance (ataxia),
- heart rhythm changes (detected usually on ECG),
- loss of consciousness, convulsions or coma.

If you forget to take Lamotrigine Normon

Do not take a double dose to make up for a forgotten dose. Carry on as usual the next day.

In case you forget to take multiple doses of Lamotrigine Normon:

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

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.

If you are taking Lamotrigine Normon for epilepsy

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

If you are taking Lamotrigine Normon for bipolar disorder

Lamotrigine Normon may take some time to work, so you are unlikely to feel better straight away. 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.

4. Possible side effects

Like all medicines, this medicine 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 lamotrigine get an allergic reactions or potentially life-threatening 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 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 (sleepiness),
- **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 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
- shaking or tremors
- difficulty in sleeping (*insomnia*)
- feeling agitated
- diarrhoea
- dry mouth
- nausea or vomiting
- feeling tired
- pain in your back, joints or elsewhere

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*)
- skin rash or sunburn after exposure to sun or artificial light (photosensitivity)

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 the beginning of section 4*)
- 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**
- 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 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 (*lymphadenopathy*) (*see also the information at the beginning of section 4*)
- changes in liver function, which will show up in blood tests or liver failure (*see also the information at the beginning of section 4*)
- a serious disorder of blood clotting, which can cause unexpected bleeding or bruising (*disseminated intravascular coagulation*) (*see also the information at the beginning of section 4*)
- changes which may show up in blood tests - including reduced numbers of red blood cells (*anaemia*), 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 anaemia
- hallucinations ('seeing' or 'hearing' things that are not 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)
- Haemophagocytic lymphohistiocytosis (HLH) (see section 2. What you need to know before you take lamotrigine)

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.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lamotrigine Normon

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the container. The expiry date refers to the last day of that month.

Store below 25°C. Store in the original package in order to protect from light and moisture.

Do not throw away any medicines via wastewater or household waste. If you are not sure, ask your pharmacist how to throw away medicines and containers you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Lamotrigine Normon 100 mg dispersible/ chewable tablets contain

The active substance is lamotrigine. Each dispersible/chewable tablet contains 100 mg of lamotrigine.

The other ingredients are: Crospovidone, sodium saccharin (E-954), orange essence (contains glucose and benzyl alcohol), magnesium stearate and colloidal silica.

What Lamotrigine Normon looks like and contents of the pack

Lamotrigine Normon 100 mg dispersible/chewable tablets are white or almost white, biconvex and round dispersible/chewable tablets.

Each pack contains blisters of 56 tablets.

Not all pack sizes are marketed in all countries.

Marketing Authorization Holder and Manufacturer

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