Package leaflet: Information for the patient

Lamotrigin Oresund Pharma 200 mg tablets
lamotrigine

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.

What is in this leaflet

1. What <INVENTED NAME> is and what it is used for

<INVENTED NAME> belongs to a group of medicines called anti-epileptics. It is used to treat two conditions – epilepsy and bipolar disorder.

<INVENTED NAME> treats epilepsy by blocking the signals in the brain that trigger epileptic seizures (fits).
- For adults and children aged 13 years and over, <INVENTED NAME> can be used on its own or with other medicines, to treat epilepsy. <INVENTED NAME> 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, <INVENTED NAME> 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.

<INVENTED NAME> also treats 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, <INVENTED NAME> 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 <INVENTED NAME> works in the brain to have this effect.

2. What you need to know before you take <INVENTED NAME>

Do not take <INVENTED NAME>
- if you are allergic (hypersensitive) 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 <INVENTED NAME>.

Warnings and precautions

Talk to your doctor or pharmacist before taking <INVENTED NAME>,
- 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 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 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 medicine that contains lamotrigine.
- if you have a condition called Brugada syndrome, or other heart problems. Brugada syndrome is a genetic disease that results in abnormal electrical activity within the heart. ECG abnormalities which may lead to arrhythmias (abnormal heart rhythm) can be triggered by lamotrigine.

If any of these applies to you:
➔ **Tell your doctor**, who may decide to lower the dose or that <INVENTED NAME> is not suitable for you.

Important information about potentially life-threatening reactions
A small number of people taking lamotrigine get an allergic reaction or potentially life-threatening skin reaction, which may develop into more serious problems if they are not treated. These can include Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). You need to know the symptoms to look out for while you are taking <INVENTED NAME>. This risk may be associated with a variant in genes in people from Asian origin (mainly Han Chinese and Thai). If you are of such origin and have been tested previously carrying this genetic variant (HLA-B*1502), discuss this with your doctor before taking <INVENTED NAME>.
➔ **Read the description of these symptoms in section 4 of this leaflet** under “Potentially life-threatening reactions: get a doctor’s help straight away”.

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

Thoughts of harming yourself or suicide
Anti-epileptic medicines are used to treat several conditions, including epilepsy and bipolar disorder. People with bipolar disorder can sometimes have thoughts of harming themselves or committing suicide. 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 about suicide
- if you are under 25 years old.

If you have distressing thoughts or experiences, or if you notice that you feel worse or develop new symptoms while you’re taking <INVENTED NAME>:
➔ **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 <INVENTED NAME> for epilepsy
The seizures in some types of epilepsy may occasionally become worse or happen more often while you are taking <INVENTED NAME>. 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 <INVENTED NAME>:
➔ **See a doctor as soon as possible.**

<INVENTED NAME> 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 <INVENTED NAME>

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

➔ **Tell your doctor** if you are taking any of these.

Some medicines interact with <INVENTED NAME> or make it more likely that people will have side effects. These include:
- valproate, used to treat epilepsy and mental health problems
- carbamazepine, used to treat epilepsy and mental health problems
- phenytoin, primidone or phenobarbitone, used to treat epilepsy
- risperidone, used to treat mental health problems
- rifampicin, which is an antibiotic
- medicines used to treat Human Immunodeficiency Virus (HIV) infection (a combination of lopinavir and ritonavir or atazanavir and ritonavir)
- hormonal contraceptives, such as the Pill (see below)

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

<u>Hormonal contraceptives (such as the Pill) can affect the way <INVENTED NAME> works</u>
Your doctor may recommend that you use a particular type of hormonal contraceptive, or another method of contraception, such as condoms, a cap or a coil. If you are using a hormonal contraceptive like the Pill, your doctor may take samples of your blood to check the level of <INVENTED NAME>. 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.

<INVENTED NAME> 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 <INVENTED NAME> is affecting the way your contraceptive is working.

Pregnancy and breast-feeding
➔ **If you are pregnant, think you may be pregnant or are planning to have a baby** ask your 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 <INVENTED NAME>, so you may need blood tests

and your dose of <INVENTED NAME> may be adjusted.
- There may be a small increased risk of birth defects, including a cleft lip or cleft palate, if <INVENTED NAME> 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 <INVENTED NAME> passes into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of breast-feeding while you are taking <INVENTED NAME>, and will check your baby from time to time, whether drowsiness, rash or poor weight gain occurs, if you decide to breast-feed. Inform your doctor if you observe any of these symptoms in your baby.

Driving and using machines
<INVENTED NAME> 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.

<INVENTED NAME> 200 mg tablets contain lactose and sodium
Each <INVENTED NAME> 200 mg tablet contains 152 mg lactose (as lactose monohydrate). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take <INVENTED NAME>

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

How much <INVENTED NAME> to take
It may take a while to find the best dose of <INVENTED NAME> for you. The dose you take will depend on:
- your age
- whether you are taking <INVENTED NAME> 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 <INVENTED NAME> than your doctor tells you to**.

Use in children and adolescents
The usual effective dose of <INVENTED NAME> for adults and children aged 13 years or over is between 100 mg and 400 mg each day.

For children aged 2 to 12 years, 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 maintenance dose of 200 mg daily.

<INVENTED NAME> is not recommended for children aged under 2 years.

How to take your dose of <INVENTED NAME>

Take your dose of <INVENTED NAME> once or twice a day, as your doctor advises. It can be taken with or without food.
- Swallow your tablets. Do not chew or crush them.
- Always take the full dose that your doctor has prescribed.

<INVENTED NAME> 200 mg tablets
The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

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.

If you take more <INVENTED NAME> than you should
➔ **Contact a doctor or nearest hospital emergency department immediately**. If possible, show them the <INVENTED NAME> packet.

If you take too much <INVENTED NAME> you may be more likely to have serious side effects which may be fatal. Someone who has taken too much <INVENTED NAME> 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, fits (convulsions) or coma.

If you forget to take a single dose of <INVENTED NAME>
➔ **Do not take extra tablets to make up for a missed dose. Just take your next dose at the usual time**.
In case you forget to take multiple doses of <INVENTED NAME>
➔ **Ask your doctor for advice on how to start taking it again**. It is important that you do this.

If you stop taking <INVENTED NAME>
Do not stop taking <INVENTED NAME> without advice. <INVENTED NAME> must be taken for as long as your doctor recommends. Do not stop unless your doctor advises you to.

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

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

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

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 <INVENTED NAME> 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

<INVENTED NAME>, especially if the starting dose is too high or if the dose is increased too quickly, or if <INVENTED NAME> 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 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 <INVENTED NAME>. In case you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis your doctor will tell you that you must never use lamotrigine again.

Haemophagocytic lymphohistiocytosis (HLH) (see section 2 “What you need to know before you take <INVENTED NAME>”).

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
- feeling sick (*nausea*) or being sick (*vomiting*)
- feeling tired
- pain in your back or 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
- Haemophagocytic lymphohistiocytosis (HLH): see section 2 “What you need to know before you take <INVENTED NAME>”
- changes which may show up in blood tests — including reduced numbers of red blood cells (*anaemia*), reduced numbers of white blood cells (*leucopenia*, *neutropenia*, *agranulocytosis*), reduced numbers of platelets (*thrombocytopenia*), reduced numbers of all these types of cell (*pancytopenia*), and a disorder of the bone marrow called aplastic anaemia
- hallucinations (‘seeing’ or ‘hearing’ things that aren’t really there)
- confusion
- feeling ‘wobbly’ or unsteady when you move about
- uncontrollable repeated body movements and/or sounds or words (*tics*), uncontrollable muscle spasms affecting the eyes, head and 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)

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 antiepileptic medication, have a history of osteoporosis, or take steroids.
- inflammation of the kidney (*tubulointerstitial nephritis*), or inflammation of both the kidney and the eye (*tubulointerstitial nephritis* and *uveitis syndrome*)
- Nightmares
- Lower immunity because of lower levels of antibodies called immunoglobulins in the blood which help protect against infection
- Red nodules or patches on the skin (pseudolymphoma).

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.
You can also report side effects directly via the national reporting system listed in Appendix V*. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <INVENTED NAME>

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 blister/label of the bottle and the carton after the EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What <INVENTED NAME> contains
- The active substance is lamotrigine.
- Each tablet contains 200 mg lamotrigine.

The other ingredients are Cellulose microcrystalline, lactose monohydrate, sodium starch glycolate (Type A), magnesium stearate, povidone, ***indigo carmine aluminium lake (E132).***

What <INVENTED NAME> looks like and contents of the pack
Tablet.

<INVENTED NAME> 200 mg tablets are blue coloured, mottled, shield shaped uncoated tablets debossed with ‘D’ and ‘96’on one side and scoreline on the other side.
The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

<INVENTED NAME> tablets are available in:
- Clear PVC/Aluminium foil blisters
  Pack sizes: 7, 10, 14, 20, 21, 28, 30, 40, 42, 46, 50, 56, 60, 90, 98, 100, 200, 250, 500 tablets.

- HDPE bottles with polypropylene cap and cotton coil
  Pack sizes: 60, 90, 100, 250, 500, 1000 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
<[To be completed nationally]>

Manufacturer
[To be completed nationally]

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Denmark	Lamotrigin Oresund Pharma
Sweden	Lamotrigin Oresund Pharma

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