Package leaflet: Information for the patient

Lamotrigine PTR Pharma 5 mg tablets
Lamotrigine PTR Pharma 100 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 Lamotrigine is and what it is used for
2. What you need to know before you take Lamotrigine
3. How to take Lamotrigine
4. Possible side effects
5. How to store Lamotrigine
6. Contents of the pack and other information

1. What Lamotrigineis and what it is used for

Lamotrigine belongs to a group of medicines called anti-epileptics. It is used to treat two conditions – **epilepsy** and **bipolar disorder**.
Lamotrigine treats epilepsy by blocking 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 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, Lamotrigine 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

Do not take Lamotrigine:
- **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 don't take Lamotrigine.

Warnings and precautions

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 Lamotrigine. 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 Lamotrigine.

➔ **Read the description of these symptoms in Section 4. of this leaflet** under 'Potentially life-threatening reactions: get a doctor's help straight away'.

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 Lamotrigine is not suitable for you.

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

Children and adolescents
Lamotrigine 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
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 Lamotrigine 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)
- **oestrogen-containing products, including hormonal contraceptives,** such as **the Pill** *(see below)* **and hormone replacement therapy (HRT)**.

➔ **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 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.

HRT can effect the way Lamotrigine works
If you are using oestrogen-containing hormone replacement therapy (HRT), your doctor may take samples of your blood to check the level of Lamotrigine.

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, so you may need blood tests and your dose of Lamotrigine may be adjusted.
- There may be a small increased risk of birth defects, including a cleft lip or cleft palate, if Lamotrigine 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 breast-feeding or planning to breast-feed ask your doctor or pharmacist for advice before taking this medicine.** The active ingredient of Lamotrigine passes into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of breast-feeding while you're taking Lamotrigine 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
Lamotrigine can cause dizziness and double vision.
➔ **Don't drive or use machines unless you are sure you're not affected.**

If you have epilepsy, talk to your doctor about driving and using machines.

Lamotrigine contains lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Lamotrigine

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

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

Use in children and adolescents
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 400 mg daily.

Lamotrigine is not recommended for children aged under 2 years.

How to take your dose of Lamotrigine

Lamotrigine is for oral use.
Take your dose of Lamotrigine once or twice a day, as your doctor advises. Lamotrigine tablets have a score line and the tablet can be divided into equal doses. Lamotrigine 5 mg tablets can be divided into equal doses (halved) and Lamotrigine 100 mg tablets can be divided into equal quarters.

- **Swallow your tablets or tablet halves or quarters whole with a glass of water. Do not chew or crush the tablets.**
- **Always take the full dose that your doctor has prescribed.** Never take only part of a dose.

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 Lamotrigine than you should
➔ Contact a doctor or nearest hospital emergency department immediately. If possible, show them the Lamotrigine packet.

If you take too much **Lamotrigine you may be more likely to have serious side effects which may be fatal.** Someone who has taken too much Lamotrigine may have any of these symptoms:
- rapid, uncontrollable eye movements *(nystagmus)*
- clumsiness and lack of co-ordination, affecting their balance *(ataxia)*
- worsening of seizures, e.g. increase in seizure frequency
- cardiac rhythm modification
- loss of consciousness, fits (convulsions) or coma.

If you forget to take Lamotrigine
➔ Don't 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 Lamotrigine
➔ Ask your doctor for advice on how to start taking it again. It's important that you do this.

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

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

If you're taking Lamotrigine for bipolar disorder
Lamotrigine may take some time to work, so you are unlikely to feel better straight away. If you stop taking Lamotrigine, 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.

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 everyone gets them.

Potentially life-threatening reactions: get a doctor's help straight away
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 symptoms are more likely to happen during the first few months of treatment with Lamotrigine, especially if the starting dose is too high or if the dose is increased too quickly or if Lamotrigine 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 serious or sometimes life-threatening skin reactions including rash with target lesions (*Erythema multiforme*), 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 Lamotrigine. 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 Lamotrigine”).

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:
- skin reaction that causes red spots or patches on the skin, that may look like a target or "bulls-eye" with a dark red centre surrounded by paler red rings (*erythema multiforme)*
- 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 Lamotrigine").
- 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 not known (frequency cannot be estimated from the available data)
- 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.
- inflammation of the kidney *(tubulointerstitial nephritis)*, or inflammation of both the kidney and the eye *(tubulointerstitial nephritis and uveitis syndrome)*
- an abnormal condition of the mind with loss of contact of the reality (acute psychotic reactions; this may include e.g. paranoid reactions, manic episodes, delusions), nightmares, obsessive-compulsive disorder

- 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 HPRA Pharmacovigilance Website: www.hpra.ie..
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lamotrigine

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 carton and blisters after EXP. The expiry date refers to the last day of that month.

This medicine 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 Lamotrigine contains
The active substance is lamotrigine.

Each Lamotrigine PTR Pharma 5 mg tablet contains 5 mg lamotrigine.
Each Lamotrigine PTR Pharma 100 mg tablet contains 100 mg lamotrigine.

The other ingredients are:

Lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, povidone, magnesium stearate, talc, silica, colloidal anhydrous, iron oxide yellow (E-172) (only 100 mg).

Lamotrigine PTR Pharma contains lactose and sodium (see section 2. "**Lamotrigine** contains lactose and sodium").

What Lamotrigine PTR Pharma looks like and contents of the pack
Lamotrigine PTR Pharma 5 mg tablets
White, round (8 mm in diameter), flat tablet with a break-mark on one side and "5" embossed on the other side.

Lamotrigine PTR Pharma 100 mg tablets
Light yellow, square shaped (dimensions 10 x 10 mm) tablet with a notch on the centre of each side, one surface is convex and the other surface is flat with a cross shaped break-mark.

Each pack contains 30, 50, 60 or 100 tablets.

Not all pack sizes may be marketed.

Marketing authorisation holder and manufacturer

Marketing authorisation holder

PTR Pharma Consulting Unipessoal Lda.
Rua Brito Pais,
8C Miraflores
1495-028 Algés,
Portugal

Manufacturer
Desitin Arzneimittel GmbH
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This medicine is authorised in the Member States of the European Economic Area under the following names:

AT	Lamotrigin ARAC
BE	Lamotrigine PTR Pharma
DK	Lamotrigin PTR Pharma
EE	Lamotrigine PTR Pharma
ES	Lamotrigine PTR Pharma
FI	Lamotrigin PTR Pharma
FR	Lamotrigine PTR
IT	Lamotrigina PTR Pharma
LU	Lamotrigine PTR Pharma
NL	Lamotrigin PTR Pharma
NO	Lamotrigin PTR Pharma
PL	Lamotrigin PTR Pharma
PT	Lamotrigine PTR Pharma
RO	Lamotrigină PTR Pharma
SE	Lamotrigin PTR Pharma

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